FEDERAL TRADE COMMISSION

I N D E X (PUBLIC RECORD)

Schering

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| SPX 711 | 2788 |
| SPX 713 | 2797 |
| SPX 714 | 2801 |
| SPX 718 | 2821 |
| SPX 720 | 2940 |
| SPX 721 | 2959 |
| SPX 723 | 2966 |
| SPX 724 | 2985 |
| SPX 746 | 3010 |
| SPX 769 | 3001 |
| SPX 2038 | 2968 |
| SPX 2041 | 2977 |
| SPX 2042 | 2986 |
| SPX 2043 | 2989 |
| SPX 2044 | 3001 |
| SPX 2045 | 3005 |
| SPX 2046 | 2803 |
| SPX 2047 | 2811 |
| SPX 2048 | 2812 |
| SPX 2049 | 2812 |
| SPX 2050 | 2813 |
| SPX 2051 | 2814 |
| SPX 2054 | 2814 |
| SPX 2055 | 2817 |

Schering

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Upsher

None

FEDERAL TRADE COMMISSION

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| In the Matter of: | ) |
| SCHERING-PLOUGH CORPORATION, | ) |
| a corporation, | ) |
| and | ) |
| UPSHER-SMITH LABORATORIES, | ) File No. D09297 |
| a corporation, | ) |
| and | ) |
| AMERICAN HOME PRODUCTS, | ) |
| a corporation. | ) |
| ---------- | ) |

Monday, February 11, 2002

10:30 a.m.

TRIAL VOLUME 13

PART 1

PUBLIC RECORD

BEFORE THE HONORABLE D. MICHAEL CHAPPELL

Administrative Law Judge

Federal Trade Commission

600 Pennsylvania Avenue, N.W.

Washington, D.C.

Reported by: Susanne Bergling, RMR

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P R O C E E D I N G S

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JUDGE CHAPPELL: Good morning, everyone.

ALL COUNSEL: Good morning, Your Honor.

JUDGE CHAPPELL: Let's reconvene docket 9297.

Do the parties have anything before we get started?

MR. NIELDS: No, Your Honor. I thought I would just tell the Court what's up for today.

JUDGE CHAPPELL: Okay.

MR. NIELDS: We have got today, Your Honor, proof regarding the K-Dur patent and the strength of the merits of the ESI patent litigation. I cannot promise that this proof will be always riveting, but we believe it is important, particularly under a rule of reason analysis, and, of course, the ultimate importance will be judged by Your Honor and perhaps later by the Commission and maybe reviewing courts, but we do believe it's an important part of our rule of reason defense, and we plan to put it on today.

I have been advised that some person perhaps standing on the other side of the podium wants to make some sort of threshold objection.

JUDGE CHAPPELL: Okay.

MS. BOKAT: No, Your Honor, I merely wanted to

introduce to the Court two of complaint counsel, Paul Nolan and Suzanne Michel, who will be handling the cross examination for complaint counsel of these witnesses.

MR. NOLAN: And yes, Your Honor, we do plan to make an objection to the introduction of the patent evidence, and if I have -- may have a minute to make this objection, please.

JUDGE CHAPPELL: I'm not going to give running objections. I don't do that. So, you're going to have to object every time you hear an objectionable question.

MR. NOLAN: Your Honor, this is a motion to --

JUDGE CHAPPELL: Haven't I already ruled on a motion regarding this?

MR. NOLAN: Your Honor, from the Bench, you said that, "Let me tell the parties right now, this is not a patent court, and I'm not going to determine whether your patent's valid or not valid."

We have a relevancy objection, because that's exactly what they plan to do today, and Your Honor --

JUDGE CHAPPELL: Well, hang on, before you go on any further, is that what you plan to do today?

MR. NIELDS: No, Your Honor, we don't plan to do that. Indeed, patent validity is not an issue. We

do plan to offer evidence that the -- given the strength of Schering's position in the ESI case, the settlement was reasonable and fair to consumers.

JUDGE CHAPPELL: Okay.

MR. NOLAN: May I respond? Thank you, Your Honor.

First of all, Your Honor -- and I'll make this very brief -- the antitrust case here that is being brought is a case related to the per se illegal nature of a payment for delay. It's not about the fairness of a patent split, of a split of a patent term.

Schering-Plough so far has not offered any efficiency justification for this payment for delay. Instead, we have heard essentially that there's the -- today we would hear about the so-called objective strength of the patent through the voices of the experts who would have testified at the original patent trial. This will be an attempt to replay the patent merits. It does not go to the efficiency justification, if there is any, for the payment for delay. And even under rule of reason, under Professional Engineers and the NCAA case, a defendant is required to come forward with an efficiency justification to explain the -- where there is a restraint on competition.

So, what I would like to finish or summarize at this point on, Your Honor, is that the -- your statement that this was not a patent case, we took that -- we took the --

JUDGE CHAPPELL: Did I say patent case or patent court?

MR. NOLAN: You said this is not a patent court, and you also said that I think what the parties thought about whether they are going to win or lose, if they're talking about settlement, they have the right to bring that forward.

The parties have not brought anything forward about whether they were going to win or lose other than that they went into a court and a judge purportedly told them that he wished that they would settle. They've offered -- even that evidence is in conflict when you look at the public record.

And now today, instead of -- they're not offering their private, confidential memos of counsel or internal memos of the company. They're bringing in independent patent experts who would have appeared in the regular proceeding. That's fine, we're prepared for that, but if that's the type of case that this is going to be, we're going to go into the patent merits as long as it takes, just like they did with our

economic expert in terms of them seeing the importance of that to our case.

We don't think this is relevant. We think relying on your statement from the Bench, we should not be hearing from patent experts. We should be hearing from Schering-Plough executives about why they made the deal -- the payment for delay with ESI.

But it's up to you, Your Honor, and certainly we'll be prepared to respond to this part of the case if we need to.

MR. NIELDS: Your Honor, there's obviously a disagreement between us and complaint counsel on the relevance of this evidence, just as there is a disagreement about whether this is a per se case or a rule of reason case. Ultimately, those issues will have to be decided by Your Honor, and then, as we said, by the Commission and perhaps reviewing courts.

JUDGE CHAPPELL: Well, go ahead and convince me why it's relevant.

MR. NIELDS: It's relevant, Your Honor, because the crucial issue in this case is whether the settlement agreements are reasonable or unreasonable, pro-competitive or anti-competitive, and relevant to that question, important to that question, is whether the settlement agreements provided more or less

competition than the likely outcome of the litigation.

JUDGE CHAPPELL: He said you were going to attempt to prove whether the patent is valid or not. Is that what you're trying to do?

MR. NIELDS: No, Your Honor, that's really --

JUDGE CHAPPELL: Because that's not relevant, I'll tell you that.

MR. NIELDS: No, that's not the issue. The issue had to do with infringement and --

JUDGE CHAPPELL: Well, are you going to try to prove whether it's being infringed upon, because that's not relevant either. The only thing I can see that's relevant is what your clients thought your chances were when you went in to enter a settlement. Whether it's infringed or not, whether it's valid or not, we're not going to decide that here, and we don't need to waste time if that's what you're planning to do.

MR. NIELDS: That is what we're planning to do, Your Honor, and obviously we will abide by the Court's ruling, but we believe that that is relevant and important.

I have a brief memorandum I could hand to the Court now that addresses the reasons why we think that is relevant and important, but that is what -- that is the issue that we plan to put on proof about.

JUDGE CHAPPELL: How is whether or not it's valid relevant? Why is it not relevant what you thought the chances were of winning when you entered into a settlement? What is -- the ultimate decision of whether it's valid or infringed upon or otherwise, how is that relevant?

MR. NIELDS: Because, Your Honor, the question in the case is whether the agreements were reasonable, whether they, in fact, fairly reflected the merits of the case.

JUDGE CHAPPELL: How do you -- logically, how does something that wasn't known to you at the time have anything to do with whether they were reasonable at the time you formed those settlement agreements?

MR. NIELDS: Your Honor --

JUDGE CHAPPELL: You're being illogical now.

MR. NIELDS: I hope I'm not. I'm certainly trying to be logical.

A good analogy, and we have this in a memo we could give to you, is courts review settlements for reasonableness in class action cases. They do that for very similar reasons to what we're dealing with here. Courts want to make sure that they protect the interests of absent class members, and so they will look at whether a particular settlement is, in fact,

reasonable given the strength of the plaintiffs' case, and they will do that by comparing the terms of the settlement with the likely outcome of the case based on the objective facts that are available and in the record.

JUDGE CHAPPELL: Is that the efficiency justification he spoke of?

MR. NIELDS: I think that is the efficiency justification, yes, Your Honor. The whole reason we're here, the whole reason we're here instead of all agreeing that this is illegal is that the agreements settled patent litigations where -- and the reason that is special is that in a -- and this is what the treatise that we cited in our trial brief says, Your Honor, Hovenkamp, but the reason that's a unique situation, the reason this is a case of first impression is that in the litigation, if Schering wins, there's no competition, and so that makes a settlement of a legitimate legal claim that there shouldn't be competition. It takes it out of per se, we believe.

JUDGE CHAPPELL: So, you don't think the intent matters, whatever anybody intended or thought about before you formed the settlement agreement. All you think that matters is whether or not the patent was infringed?

MR. NIELDS: What the likely outcome of the litigation would have been in fact, just as it is in a class action settlement. The courts in class actions don't interrogate counsel or ask for their privileged documents. They look at the objective merits of the case, and they line that up against the terms of the settlement.

JUDGE CHAPPELL: Well, we don't know what the outcome would have been, because you didn't finish the litigation.

MR. NIELDS: You don't, just as you don't in a class action settlement, Your Honor. You don't know what the outcome is, but it is relevant whether the outcome in the settlement lines up sensibly with the merits of the case. And as I say, and when courts review settlements in the class action context, that's exactly what they address.

MR. NOLAN: Your Honor, we're not here because we're looking at just the general settlement of a patent case. Complaint counsel's allegation is that there was a payment for delay, which distinguishes this from other settlements of these sorts of cases. What -- with all due respect to respondents' counsel, what he's essentially arguing to you is that a -- an action that may be per se illegal can be justified

because -- in the form of, for instance, price-fixing, let's compare that, the reasonableness of the price, that in this case you can make a payment for delay, but if the settlement -- if there's a reasonableness of the settlement, you don't -- somehow that provides an efficiency justification.

That is not a justification for this conduct, and we're focusing the case on the payment for the delay and the reasons why in this case you've mentioned they're entitled to bring forward reasons of why they thought or what they thought about the strength of their case, but to retry the patent infringement case here today will entail a lot of time, and under the rule of relevancy, I think it will be a waste of time.

Thank you, Your Honor.

MR. NIELDS: Well, Your Honor, they have taken the position and I think their economic expert has taken the position, hat any time there is a payment at all in connection with a settlement like this, it will always result in a settlement that is worse for consumers than litigating would have been. That's his opinion. That's their case. It's a per se case, in effect.

We believe that is not true. Our economists will testify that that's not true, that their economist

is incorrect about that, and that the only way you can really determine whether the settlement was better than litigating is by taking a look at the merits of the case.

JUDGE CHAPPELL: So, your intent is to put on witnesses and at the conclusion of this case have a conclusion of law that your patent was valid, invalid or infringed or not infringed?

MR. NIELDS: No, I think Your Honor has made it clear that you will not rule on that.

JUDGE CHAPPELL: Then why do we need to hear it?

MR. NIELDS: Because what we're asking for, Your Honor, is something slightly different, and it's the same thing that happens in class action cases. What we're asking for is a ruling from Your Honor that the settlement fairly reflected the likely outcome of the case, and that's the reason we're putting this proof on now, and that's the purpose of the proof.

JUDGE CHAPPELL: And are you saying that the likely outcome is more important than what your clients thought the likely outcome would be when they entered into the agreement?

MR. NIELDS: Yes, because the more important question, Your Honor, is whether the agreements

actually are reasonable, whether they actually deliver as much competition as one would have expected in the litigation.

MR. NOLAN: One further point, Your Honor. Respondent's counsel describes the agreements in general. I think it's important, taking a look at complaint counsel's complaint, that we're referring to the payment for delay. It's a central feature of our case. That is where the question is, is that per se illegal or reasonable under any analysis of antitrust laws, not whether or not the entire settlement agreement in some other sense is reasonable or unreasonable. So, I do believe that respondent's counsel is casting this in a -- in a characterization that's broader than the antitrust complaint allegation.

We would be prepared to consider some sort of proffer of evidence in this area if that would supply the Court with some measure of comfort in terms of a portion of the record, but we think that to go through the original experts in the patent case who are going to talk about very technical, highly scientific matters, we would be compelled to do our job and to go through that just as though we were doing a patent case.

JUDGE CHAPPELL: Anything further?

MR. NIELDS: Perhaps I should mention one other thing further, Your Honor. We are addressing the same issue that they're raising. One of the Commissioners, speaking obviously only for himself, has talked about this issue, the exact same issue that we're discussing here today, and he has indeed -- he's given two speeches on it, and he's given slightly different thoughts about the issue in the two speeches, but the question that he addresses and the question that this Court will have to address and eventually the Commission is whether they're right, that any time there is any payment, that automatically proves that the agreement provides -- the settlement provides less competition than the likely outcome of the litigation. That's their view. That's their argument. They're going to present it to Your Honor, and eventually they are going to present it to the Commission.

JUDGE CHAPPELL: Right, but that Commissioner was commenting in general. He wasn't commenting on the way this complaint is set up, the way this case is alleged.

MR. NIELDS: I'm not sure about -- I'm not sure about that, but in any event, he is addressing the general issue of settlements of patent disputes that involve some payment, and he's struggling with the

issue of do you have to look at the merits of the patent case? Is there some other way of getting at that question without looking at the merits of the patent case? But always saying that the crucial, ultimate issue is how does the settlement compare in terms of the competition that it produces with the likely outcome of the litigation, remembering that in this kind of settlement, the settlement clearly produces a lot more competition than if Schering had won, because in both cases the generic got into the market earlier than they would if Schering had won. So, that's the issue.

They're going to be arguing that you don't need to look at the patent proof, that if there's any payment at all, that's the end of the case. It's a per se rule. That's their position.

Our position is you can't make a per se rule out of it. You have to look at all of the relevant evidence, and the one very important type of evidence to look at is how strong was the plaintiff's case. And as I think I've said in opening statement, what we will prove here -- and we will do it efficiently and we think very understandably, Your Honor. You will have to decide that. If you don't think this proof is clear and convincing and understandable, you won't give it

any weight.

But we think we can put in very clear and very convincing evidence that ESI's defense was essentially based on the idea that two ingredients in their tablet coating were not mixed, and what happened was there were scientific studies done that showed they were, and that -- it was very strong evidence, and we had a very strong case.

We don't -- we don't purport to try to be mathematical about it, but I -- we believe, Your Honor, that after listening to this evidence, you will regard it as very important in judging whether the ESI settlement was fair to consumers.

MR. NOLAN: Your Honor --

JUDGE CHAPPELL: Mr. Curran?

MR. CURRAN: Yes, Your Honor, I understand that the witnesses being proffered today will testify only about the ESI-Schering patent litigation, but because Your Honor's consideration of this issue may impact Upsher-Smith at a subsequent point, I would like to make it clear that on behalf of Upsher-Smith, we believe that the merits of the patent case -- cases ought to be considered, and I would link that directly, Your Honor, to the complaint and the way it's -- the allegations in the complaint read.

Paragraph 63 of the complaint alleges that the acts of the respondents had the purpose and effect of restraining competition.

Paragraph 67 says, "As a result of respondents' conduct as alleged -- as herein alleged, consumers are being deprived of the benefits of competition from Upsher-Smith, ESI or other generic competitors."

Your Honor, as Mr. Nields said, the rule of reason requires consideration of all relevant facts and circumstances. We submit that this case could not be considered the way it's alleged and under the rule of reason without some consideration of the merits of the underlying patent cases.

MR. NOLAN: Your Honor, whenever people mention patents and the patent cases, it's a little bit like Moses, the idea of the waters part and it must have been a wonderful patent and certainly there was infringement. If we try this patent case here, I can vouch that the evidence that we will develop will be contrary to that, and the case is not as strong in any respect as they say.

What I would like to suggest is that a reasonable accommodation of the Court's time would be for the parties to select a few items, perhaps expert reports or what have you, make some sort of limited

proffer that doesn't take the Court's time here, because if we go into this area, no matter how streamlined their management of that aspect of the case may be, we'll have -- I have no choice except to draw out the facts as best I can with respect to the so-called strong patent case, and that's going to take time.

So, you know, I think that the parties ought to come together and consider some sort of agreement that takes this away, off of the trial proceeding today, and lets the antitrust case proceed.

JUDGE CHAPPELL: Have you discussed this proffer with the other side?

MR. NOLAN: I mentioned to one of the associate counsels this morning the idea, but we didn't have a chance to discuss it at any great length.

MR. NIELDS: It's the first I've heard of it, Your Honor. The reason -- you know, we've been doing this, both sides, for months, and the purpose of the expert reports was precisely in order to summarize and synthesize for the Court. We have our three patent witnesses here today. We are optimistic we can have them on and off today. We don't have anyone else today, and I don't believe this will take the Court's time, and I think -- it won't take any extra time, and

I believe that Your Honor will be in a better position to judge whether you think this is important evidence after you've heard it.

JUDGE CHAPPELL: Summarize what these three witnesses are supposed to tell us.

MR. NIELDS: I'm sorry?

JUDGE CHAPPELL: Just give me a summary of what these three witnesses are here to say.

MR. NIELDS: The first witness will be Dr. Langer, Your Honor. He is a scientist who subjected the ESI tablet coatings to analysis and concluded as a result of his analysis that those -- that the materials in the coating were mixed.

The last witness will be Charles Miller, who has reviewed the evidence that was to be offered by both parties and the briefs that have been filed in the case, if the case had been fully discovered, and he will summarize that for the court, the legal positions and the factual positions and the factual evidence, and the essential nub of it is going to be that the main defense was that the two ingredients in ESI's coating were not mixed, and ESI took the position that the patent wasn't infringed unless they were mixed, and he will render the opinion that Schering's case was very, very strong, particularly given the fact that the

scientific evidence showed that the coatings were mixed, the ingredients in the coatings were mixed.

And then, Your Honor, Dr. Gilbert Banker will simply educate the Court about what the nature of this invention and this patent was, what the problem was that Schering's patent solved that made the K-Dur patent a useful and important invention.

MR. NOLAN: Again, Your Honor --

JUDGE CHAPPELL: So, Counselor, are you claiming surprise that you didn't know what they were going to say?

MR. NOLAN: Well, there's two aspects here --

JUDGE CHAPPELL: Hang on, only one of us can talk at one time.

MR. NOLAN: I'm sorry, Your Honor.

JUDGE CHAPPELL: Do you want to go ahead?

MR. NOLAN: There's two aspects, Your Honor. One is that these witnesses do not reflect what the parties thought. They reflect what the experts thought, and that is a different world not subject to what was going on inside the company in terms of the things they kept from us in terms of their privileged documents, which is fine, but this is not what the parties thought, and your statement from the Bench was what the parties thought about whether they were going

to win or lose.

And moreover, in terms of notice and what's fair, Your Honor said, "Let me tell the parties right now, this is not the patent case," and when you went on to refer that you weren't going to try whether the patent's valid or not valid. I think it's fair to assume within that you also meant infringement, and yet, even though you made that remark on the 25th -- Friday, the 25th of January, we're seeing these expert witnesses come in today like you never said that from the Bench, and I think that's unfair.

JUDGE CHAPPELL: Well, it was like I told Mr. Nields, I think their chances of winning, I think that's relevant. Whether the patent was infringed or not, we're not going to determine that. It's not the patent court. That's down the street or a few blocks from here anyway.

Did you say you had something in writing?

MR. NIELDS: I do, Your Honor.

JUDGE CHAPPELL: A motion or a memorandum, what is it?

MR. NIELDS: Just a memorandum. I've essentially summarized it already, but I'm happy to hand it up if the Court will find that useful.

JUDGE CHAPPELL: Has that been given to

complaint counsel?

MR. NIELDS: No, I have not filed it or served it. I learned that this issue was going to come up not long ago.

JUDGE CHAPPELL: How long is your memorandum?

MR. NIELDS: Two pages.

JUDGE CHAPPELL: If I look at it, you are going to have to let complaint counsel respond to it in writing.

MR. NIELDS: It might be more efficient, Your Honor, given that we've got our witnesses here today and we have another set of witnesses coming tomorrow if we simply went ahead with the proof and the Court can decide at whatever point what weight you want to accord to it.

JUDGE CHAPPELL: Based on the offer made by complaint counsel, do the parties want to take a short break and talk about some kind of an agreement or stipulation on this issue?

MR. NOLAN: That would be fine.

MR. NIELDS: Your Honor, I don't see how we can do a stipulation, because they have their experts who have already done their analysis and they take a different view, and I think they're entitled to have their experts try to convince you that ours are wrong.

We are pretty confident they won't succeed in that, but they're entitled to do it. There is not an agreement between the parties as to what the evidence shows, I don't think.

MR. NOLAN: Your Honor, we'd be willing to talk with Mr. Nields and the other parties, with Upsher, about withdrawing our rebuttal patent experts if there was a suitable arrangement that was reached where this evidence was put forward in some proffer, some defined proffer as opposed to something where, you know, we would just go on for several days on this. So, we're willing to talk to the other side. We'd be willing to make a good faith effort to reach an agreement if they're willing to put their witnesses aside.

MR. NIELDS: Your Honor, I would -- if I thought that some fruit could come of this, I would leap at the opportunity, but as I've said, none of this is new. Nothing is surprising. We've had these expert reports for months. We've done depositions. We've taken depositions of their experts. They've taken depositions of ours. And we have our witnesses here today ready to testify. They've known that they were coming for a long time, and it seems to me we will cause not convenience of the Court but inconvenience to the Court by interrupting the proceedings, having a

debate about what the -- what the right answer is, and not being able to agree, and then having to come back and present the evidence.

JUDGE CHAPPELL: Tell me again why I have to hear someone tell me whether or not your patent was infringed if I don't need to make a conclusion of law on that issue.

MR. NIELDS: For the reason that Your Honor mentioned just a moment ago. We're not asking the Court to decide the patent case at this point. The Court's made it very clear you're not going to do that. What we are doing is we're asking the Court to perform the same role that a federal judge does in reviewing the reasonableness of a class action settlement, and that is to compare the evidence in the patent case with the settlement. That will put Your Honor in a better position, under the rule of reason, to judge whether the settlement was fair to consumers in the sense of whether the settlement produced as much competition as the likely outcome of the litigation.

JUDGE CHAPPELL: What's your response to why that's not allowed?

MR. NOLAN: Well, again, it's saying that a payment for delay essentially can be made fair on some other ground, that in effect, you can fix a fair term

of the patent, just like you can fix a fair price. That's not the law. It's an antitrust matter. Even in rule of reason, you have to have a pro-competitive justification.

In addition, they are saying, Your Honor, that they thought that they would win, and they're doing that through the pristine voices of their patent experts as opposed to the voices of their executives. The experts may have thought anything about the strength of the case, and as lawyers, we all know that experts to some extent are kept in their own particular places to talk about their own particular areas of expertise. They don't know about the -- they know a lot about who's going to testify in the battle of experts, but they're not well positioned to say anything about the strength of the overall case.

JUDGE CHAPPELL: Like I told Mr. Orlans I think it was Friday, you know, that goes to the strength of their defenses and to their arguments if there's some missing direct link because they're hiding behind a privilege, and you have the right to make that argument, and I think your -- what we're getting into now are legal issues, and we don't have a jury here. We have people sitting here ready to testify, I'm sure from out of town, some of them, and when this is all

over, the legal issues can be raised, can be briefed and I'll rule on them, but I'm going to overrule -- is it a motion or an objection?

MR. NOLAN: It's a motion, Your Honor.

JUDGE CHAPPELL: The motion is denied. I am going to allow the witnesses to testify. You're free to object whenever you think you need to. Let's proceed.

MR. NOLAN: Thank you.

MR. NIELDS: Thank you, Your Honor. Is that -- maybe I didn't mention this --

JUDGE CHAPPELL: Let me say as I did in this ruling, this is not the end of this issue legally. The parties are welcome to open this up, brief it as you think you must in your post-trial briefs.

MR. NIELDS: Thank you, Your Honor.

My partner Joseph Lavelle will be actually putting on this proof. This is Mr. Lavelle.

MR. LAVELLE: Good morning, Your Honor.

JUDGE CHAPPELL: Good morning.

MR. NIELDS: And my colleague, Vivian Kuo, will be helping him, and he will call the witness.

JUDGE CHAPPELL: All right. Well --

MR. LAVELLE: Our first witness is going to be Dr. Robert Langer, Your Honor.

JUDGE CHAPPELL: Raise your right hand, please.
Whereupon--
ROBERT S. LANGER
a witness, called for examination, having been first duly sworn, was examined and testified as follows:
JUDGE CHAPPELL: State your full name for the record, please.
THE WITNESS: Robert Samuel Langer.
MR. LAVELLE: Your Honor, we have exhibit books that we would like to pass up to you and to counsel.
DIRECT EXAMINATION
BY MR. LAVELLE:
Q. Good morning, Dr. Langer.
A. Good morning.
Q. Dr. Langer, where do you work?
A. I work at the Massachusetts Institute of Technology, MIT, and Harvard Medical School.
Q. And what do you do there, sir?
A. I'm a scientist and a professor.
Q. What do you teach?
A. I teach a number of courses in chemical engineering and drug delivery systems and biotechnology.
Q. And are you also a researcher?
A. Yes, I am.

Q. And in what areas is your scientific research directed?

A. Drug delivery systems and biomaterials.

Q. How long have you been at MIT, sir?

A. I've been on the faculty since 1977, 25 years.

Q. Thank you, sir.

Have you performed original research in the field of pharmaceutics and drug delivery?

A. Yes.

Q. And approximately how many papers have you published in the field?

A. Seven hundred.

Q. And what was the -- if you can characterize it generally, the principal subject of those papers?

A. Again, they would generally be in the areas of drug delivery systems and biomaterials.

Q. Do you hold any patents, sir?

A. Yes.

Q. Approximately how many?

A. Four hundred, either issued or pending.

Q. Thank you, sir.

And in general, in what fields are they?

A. Also in drug delivery systems and biomaterials.

Q. Thank you.

Do you do consulting work for companies in the

drug industry?

A. Yes.

Q. Do you do consulting work for generic companies?

A. Yes.

Q. And do you do consulting work for branded pharmaceutical companies?

A. Both, yes.

Q. Have you done any work for Schering in the past?

A. Yes.

Q. Okay. Have you done any work for any of the other parties, ESI or Upsher-Smith?

A. I've consulted for American -- divisions of American Home Products, which ESI I guess is a part of.

Q. Okay, thank you, sir.

Sir, in your exhibit book, would you turn to Exhibit SPX 711 and tell us what that is, sir.

A. It's my curriculum vitae, my resume.

Q. Is it reasonably up to date and correct as far as you know?

A. Reasonably, yes.

Q. Thank you, sir.

Sir, you've been elected to three national academies, have you not?

A. Yes.
Q. The National Academy of Sciences?
A. Yes.
Q. The National Academy of Engineers?
A. Yes.
Q. And the Institute of Medicine of the National Academy of Sciences?
A. Correct.
Q. What are those national academies?
A. The National Academy of Sciences was established by Abraham Lincoln in 1863 originally to award the most outstanding scientists in the United States, so every year there's about 60 people elected in different disciplines. And then in 1964, that -- there wasn't something to do that for people involved in engineering, so they established in 1964 the National Academy of Engineering. And again, there wasn't something that specifically focused in on medicine, so they established in 1970 the Institute of Medicine of the National Academy of Sciences for people focused in there. So, they have probably about 500 members of the Institute of Medicine in the United States. Each of them are the most sort of significant honoraries in the country for the particular field.
Q. And in the United States today, how many people

are there who have been elected to all three of those academies and are active in all three?

A. I'm the only one.

Q. Thank you, sir.

Sir, have you won the Distinguished Pharmaceutical Science Award from the American Association of Pharmaceutical Scientists?

A. Yes.

Q. What is that award and why were you given it?

A. The American Association of Pharmaceutical Scientists is the -- kind of the main scientific organization for people who do, you know, sort of pharmaceutical-related research. That's their highest award.

Q. How many people have received that award?

A. Six.

Q. Have you received an award from the Gairdner Foundation, sir?

A. Yes.

Q. And what is that award, sir?

A. That's the award that -- they give an award for the most outstanding medical research in the world each year.

Q. And historically, what has the receipt of that award suggested or signified?

A. It's been one of the most consistent predictors of the Nobel Prize; 56 people who won it subsequently received the Nobel Prize.

Q. Have you been featured in Time Magazine's publication, America's Best in Science and Medicine?

A. Yes.

Q. And for what part of your work did you receive that honor?

A. So, they chose what they felt at Time Magazine last year the 18 most significant people in science and medicine, and they chose me for the work in drug delivery systems.

Q. Have you received something called the Lemelson Award, sir?

A. Yes.

Q. What is that award?

A. That's the most significant award for invention in America.

Q. Thank you.

Are you a member of the Controlled Release Society, sir?

A. Yes.

Q. Are you a member of the American Institute of Chemical Engineering?

A. Yes.

Q. Are you a member of the American Chemical Society?

A. Yes.

Q. Are you on the Science Advisory Board of the Food and Drug Administration?

A. Yes, I'm its chairman.

Q. Thank you, sir.

Your Honor, I am going to offer Dr. Langer as an expert in the field of drug delivery systems at this point.

MR. NOLAN: No objection, Your Honor.

JUDGE CHAPPELL: He's accepted.

MR. LAVELLE: Thank you, Your Honor.

JUDGE CHAPPELL: I'm assuming there were no objections from you, Mr. Curran?

MR. CURRAN: No objection, Your Honor, thanks for asking.

JUDGE CHAPPELL: Thank you.

You may proceed.

MR. LAVELLE: Thank you, Your Honor.

BY MR. LAVELLE:

Q. Dr. Langer, were you a witness in the lawsuit between Schering and ESI?

A. What do you mean by "witness"?

Q. Did you prepare an expert report that you were

prepared to explain on the stand if the case went forward?

A. Oh, yes.

Q. Okay, thank you.

How did you become involved in that lawsuit between Key and ESI?

A. I was contacted by some lawyers at Covington & Burling. They asked if I would consider or try to think of ways to do experiments to examine a particular issue.

Q. And what was the issue you were asked to examine?

A. The issue was whether -- the whole issue focused on whether -- there were two layers, and whether -- I guess ESI claimed that those two layers were completely separate and distinct, and so the question was, is that true? Are these two layers of this potassium -- covering the potassium, are they totally separate and distinct layers, or rather, would there be some intermixing?

Q. So, you were told ESI had a potassium chloride product?

A. Yes.

Q. And you were told it had a coating?

A. Yes.

Q. And did you understand what that coating was made up of?

A. Yes.

Q. What materials were they?

A. There are two different polymers, ethylcellulose and hydroxypropylcellulose, EC and HPC.

Q. And what were you asked to determine about that coating?

A. Was whether -- was were they totally separate and distinct. In other words, were there two coatings separate and distinct? In other words, maybe a way to look at it is do I have one layer with one hand and one layer with the other hand (indicating), or could there be some intermixing?

Q. Were you given some samples to study?

A. Yes.

Q. What were you given, sir?

A. We were given samples of ethylcellulose, hydroxypropylcellulose, what's called an intermediate, so the way -- the intermediate is the potassium with just one of those layers on it before they put the second on.

Q. So, did the intermediate have the ethylcellulose layer?

A. Yes.

Q. But it did not have the HPC sprayed on yet?
A. Correct.
Q. And were you given any other samples?
A. And then the final system, the final -- with everything, they call that the compressible.
Q. Okay. And the compressible had both the ethylcellulose and the HPC applied?
A. Correct.
Q. Okay, fine.
What did you do to determine, you know, what kind of testing should be done?
A. Well, I have a -- several -- a number of people who work with me in the lab and people that I collaborate with. So, I got them together. We brainstormed about what kinds of tests would tell us whether they were separate and distinct or whether there might be some intermixing, and we came up with some ideas for some tests.
Q. And what tests did you decide to run, sir?
A. We did some microscopy to get a physical picture of what they looked like. We did what's called infrared spectroscopy to get a more molecular-level picture. And we did differential scanning calorimetry to look at what's called melting behavior, because there's a way, as I'll probably get to explain, where

if you could change melting behavior, you'd know that there might be some intermixing.

Q. And why did you select those three tests, sir?

A. Because they would be three totally separate ways of attacking the problem, and depending on what we saw, that would tell us whether they were separate and distinct or whether they were not separate and distinct.

Q. Okay. Are those three tests, the spectroscopy, the infrared and the calorimetry, are they generally accepted tests in the field of drug delivery systems?

A. Yes.

Q. Okay, fine, thank you, sir.

In conducting your tests, did you take any steps to ensure that your results were repeatable?

A. Well, we did them many, many times.

Q. Okay. And why do you do the tests many, many times?

A. To try to make sure that you get what we call a reproducible result.

Q. And is there a concept of having controls when you perform an experiment?

A. Yes.

Q. And did you have some controls in the tests that you did?

A. We did a number of controls. The point of controls is to pick systems that are very like what you're trying to check to make sure -- so that you can see what they look like and compare them to the results that you get.

Q. Did you go ahead and run the tests that you described for us?

A. Yes, my associates did, yes.

Q. Would you take a look at Schering Exhibit SPX 713 in your book, sir.

A. Yes.

Q. Have you got that? What is that, sir?

A. That's a report that was written by Dr. Edith Mathiowitz under my supervision where she did studies looking at the scanning electron microscopy and the infrared spectroscopy.

MR. NOLAN: Your Honor, we have an objection. This report was -- the tests in this report were not performed by Dr. Langer, were done at a different site and not under his physical supervision.

JUDGE CHAPPELL: Is that -- what's your legal basis?

MR. NOLAN: That -- essentially --

JUDGE CHAPPELL: Hearsay?

MR. NOLAN: -- he has no direct personal

knowledge of how these tests were done, because he wasn't there.

MR. LAVELLE: Your Honor, let me make a proffer of evidence here, and I think I can clear that up for you.

JUDGE CHAPPELL: You are going to lay a foundation?

MR. LAVELLE: I am going to lay a foundation for the document.

JUDGE CHAPPELL: The objection is overruled at this time.

BY MR. LAVELLE:

Q. Dr. Langer, the test results that are set forth in Exhibit 713, what was your involvement in doing this testing?

A. So, basically the way we do these tests are the same way we do them in my 700 publications that have come out in all the scientific journals, and what I did is I thought about what tests to do. I thought about which one of my associates or collaborators could do the tests. I went over with her the general design of the experiments. I then, when she got -- it's like taking photographs. So, then I took a look at the photographs with her. We actually had five different people together look at these photographs, you know, to

try to make an assessment about what they meant. So, basically I tried to use the same standards that we used on all the things that I published in the scientific literature.

Q. Did you review the results of the testing with Dr. Mathiowitz?

A. Oh, absolutely, her and others.

Q. Did you review Exhibit 713 in the drafting process?

A. Yes.

Q. Do you agree with and adopt the conclusions in Exhibit 713?

A. Yes.

Q. In preparing Exhibit 713, did you do anything different from the way you do research day to day in your lab?

A. No, as I said, this is what we always do, what I've done for 25 years in the scientific community.

MR. LAVELLE: Your Honor, I believe the document's entitled to come into evidence as the report of his scientist.

MR. NOLAN: Your Honor, we would just add that the test was done at a different university. The Exhibit 713 says nothing about how many slides were taken or how the slides that are in the report got into

this report. We don't think it's reliable, but that's -- that's our objection.

JUDGE CHAPPELL: Are you offering it as something he relied upon in his opinion or are you offering it as evidence?

MR. LAVELLE: I'm offering it as evidence of his report that he -- that was prepared as a result of the research being done.

JUDGE CHAPPELL: Give me a legal basis for your objection.

MR. NOLAN: The legal basis is the Federal Rules require personal knowledge. Dr. Langer was not there, did not see this test being done. Even with his best efforts at remote supervision, we can't be certain how the test was done, how many slides were taken, and the report itself on its face doesn't tell us that. So, there's no indicia of sufficient reliability for this expert to be testifying about this document.

MR. LAVELLE: Your Honor, the test data and photographs that are a part of the report are attached to the report. The witness has reviewed them personally and is here to testify and vouch for them. The document should come in.

MR. NOLAN: Let me just add that in any scientific research, it's of paramount importance to

know what the design and the protocol is. This report is so minimal, it has no design, no protocol in it. It does not say how these particular slides got into this report and which ones were kept out.

JUDGE CHAPPELL: I'm hearing a lot of arguments about the reliability. I'm going to not allow it to be offered. It will not be accepted as evidence at this time. You can offer it later, but I'm going to allow him to test reliability on his cross. So, at this time, I'm not admitting it into evidence.

MR. LAVELLE: Okay.

BY MR. LAVELLE:

Q. Would you take a look at Exhibit Number 714, SPX 714 in your book?

A. Yes.

Q. Would you identify this report for us, Dr. Langer?

A. This is a differential scanning calorimetry report.

Q. Okay. And what were the circumstances under which this report was prepared?

A. Well, again, this was one of the other studies that we did, and I had one of my post-doctoral fellows, Jeff Hrkach, do this work for me at MIT.

Q. Okay. Who selected what work would be done to

go into the reports that are Exhibits 713 and 714?

A. I did -- I did along with Jeff on 714 and Edith on 713.

Q. Okay.

A. I should add that we gave -- I don't know what's appropriate or not, so if I'm going beyond the bounds, we gave ESI all the notebooks they asked for and everything else that -- you know, the background science on everything that was requested. So, the point is that we did provide them with all of the things that were just discussed, which is what --

Q. What -- go ahead.

A. So, in other words, every -- all the scientific -- all the science, every single page of data that was or wasn't, so to speak, included was given to the ESI attorneys and their experts on both this and on the SEMs and the FTIRs.

Q. Are you knowledgeable about the methodology that was used in all of the tests that are recorded here?

A. Yes, we've published a number of papers, you know, where we used these methodologies.

Q. Okay. And have you reviewed the results of all of the reports that are in 713 and 714?

A. Yes.

Q. Thank you, sir.

Sir, I'd like to talk about your scanning electron microscope work.

A. Okay.

Q. Would you turn to Schering Exhibit 2046, SPX 2046 in your book.

A. Yes.

MR. NOLAN: Your Honor, we have an objection that the originals of these slides have not been found, and this is the type of evidence that generally proof is desirable in the form of an original.

MR. LAVELLE: We have made a diligent attempt to locate the originals. They're over five or six years old, and we have not succeeded in locating the originals. They are the best copies that we have. We think they're clear, and they were more than adequate for cross examination in his deposition.

JUDGE CHAPPELL: Why are they being offered? Why are they being displayed? Why are they being referred to?

MR. LAVELLE: The witness will testify that they took these photographs and there is no mixing in these photographs, mixing between the ethylcellulose layer and the HPC layer.

JUDGE CHAPPELL: So, he is going to give an

opinion based on his review of these slides?

MR. LAVELLE: Yes, sir.

JUDGE CHAPPELL: You are not offering the slides themselves, are you?

MR. LAVELLE: I am not offering the slides themselves at this time. They are part of that report, 713, but what he's about to do here is to testify based upon his review of the original of these slides.

JUDGE CHAPPELL: You're objecting to the slides or you're objecting to him testifying about the slides?

MR. NOLAN: I'm objecting to the slides coming in as evidence, because they are not the original, but we have no objection to his testifying about the slides.

JUDGE CHAPPELL: Okay, so, the objection is withdrawn at this time?

MR. NOLAN: Yes, Your Honor.

JUDGE CHAPPELL: Thank you.

You may proceed.

MR. LAVELLE: Thank you, Your Honor.

BY MR. LAVELLE:

Q. Do you recognize the micrographs that are shown in Exhibit SPX 2046, Dr. Langer?

A. Yes.

Q. Okay. I'd like you to walk through a few of

these with us and tell us what they are. What is Figure 1 a photograph of, sir?

A. It's of Ethocel, that's the first of the two putative substances being put on the potassium.

Q. And you used the brand name, Ethocel. What is the chemical?

A. Ethylcellulose.

Q. Okay. And what is shown in Figure 2, sir?

A. And that's the hydroxypropylcellulose or HPC.

Q. Briefly, would you explain how these pictures were taken?

A. Yes. Basically they're done by what's called a scanning electron microscope, so you coat the particles and then you put them through this -- you look at it through this very high-powered microscope, and it gives you sort of very detailed pictures of them.

Q. And is that what was done in this case?

A. Yes.

Q. Okay. What is Figure 3a through d a picture of?

A. So, what happened was we were given three sets of what we call intermediates, that's without the last coating applied, and this was one of those sets of those intermediates, and they're just different views of them and different magnifications. So, 3a and 3b

look at them sort of, you know, straight on, and 3c and 3d, we've kind of cut a cross-section through them, so you can see this whole issue about where the potassium is and where, say, the ethylcellulose is.

Q. Okay, and the Figure 3 is the potassium chloride with the ethylcellulose but without the HPC. Is that right?

MR. NOLAN: Objection, leading.

JUDGE CHAPPELL: Sustained.

MR. LAVELLE: I think some -- all right.

THE WITNESS: I can -- should I take people through -- I --

JUDGE CHAPPELL: You have to wait for a question.

THE WITNESS: I'm sorry, okay.

JUDGE CHAPPELL: We just had an objection, and it was sustained, so we need another question.

THE WITNESS: I see.

BY MR. LAVELLE:

Q. Would you just be clear for us, please, on what sample is shown in Figure 3 and in particular what materials are and are not on the potassium chloride?

A. I'm not sure I fully understand the question.

Q. Okay. You said that Figure 3 is a picture of the intermediate. Is that right?

A. That's correct.

Q. Okay. And what is the coating on the intermediate?

A. Ethylcellulose.

Q. Okay. And has the HPC been applied to the intermediate?

A. No.

Q. What is shown in Figure 4, sir?

A. That's where the HPC has been applied to the -- to the intermediate.

Q. Okay. And what do Figures 4a through d show with respect to this crystal?

A. They show -- they're sort of analogous to the ones in Figure 3 except now the HPC has been applied.

Q. Okay. And what are -- what are shown in Figures 5, 6, 7 and 8 generally?

A. So, Figure 5 is like Figure 3; it's another batch of intermediates, a different lot. Figure 6 is like Figure 4; it's another batch -- in fact, it's the batch from Figure 5 -- of the situation where you coat it with the HPC. And Figures 7 and 8, same thing, in other words, just another batch. So, the odd numbers correspond to the system where you don't have the HPC, and the even, you have everything, the EC and the HPC.

Q. Okay. Did you review all of the SEM

micrographs that were taken?

A. Yes.

Q. Okay. What conclusions did you draw based on your review of these SEM photographs?

A. We had five different people read them, and we really couldn't see any evidence of distinct and separate layers, comparing Figure 3 -- in other words, maybe just to pick one of them out to go over it, if you take a look at Figure -- am I --

MR. NOLAN: Your Honor, we have an objection in terms of having five people read them, and to the extent that his testimony is about what the other people said or didn't say, we believe that's objectionable hearsay and unreliable.

JUDGE CHAPPELL: Well, Federal Rule 703 allows him to base his opinion on other people's opinions, and you have the right to get into that on cross. It --

MR. NOLAN: Thank you.

JUDGE CHAPPELL: -- goes to the weight rather than the admissibility.

MR. NOLAN: Thank you, Your Honor.

JUDGE CHAPPELL: So, the objection is overruled.

BY MR. LAVELLE:

Q. Dr. Langer, would you tell us again what

conclusions you reached based upon your review of all the SEM photographs?

A. Yeah, we couldn't see -- and I'm happy to just speak for myself, I think the others are just confirmation, it's just the way we do science, makes it more reproducible to have more people look at it, but what I felt from looking at them then and now are that basically you can't really see significant differences between the odd numbered photographs in terms of this layering and the even numbered photographs in terms of this layering. So, at least from the standpoint of the scanning electron micrographs, we couldn't see evidence of separate and distinct layers coating the KCl.

Q. Okay. Would you look at Figure 8d within Exhibit SPX 2046 for a moment.

A. Yes.

Q. Is there any evidence of layering shown in Figure 8d in your opinion?

A. I don't see any evidence there, no.

Q. Okay. And would you explain that for us, please?

A. Well, again, what you want to think about are two things. One, compare it to layer 7d. Two, if there was layering, you could also figure out what those ratios would be. In other words, there's one

part of HPC for roughly every 15 parts of ethylcellulose. So, if there was layering, you would expect to see a layer that would be one-fifteenth. You don't see anything like that.

Q. Okay, thank you, sir.

I'd like to turn next to your infrared tests.

A. Yes.

Q. Would you explain to us briefly what the infrared testing that you had performed was?

A. Yes. Basically infrared is a way -- that's a certain wavelength of light, and you shine it -- you allow this light to cast into the molecule and see what gets absorbed. And from that, you can actually get sort of what I'll call like a fingerprint of the molecule, and so that's the whole idea of these F -- of these IRs is to try to get a molecular fingerprint.

Q. Okay. And did you perform infrared testing on the samples you were provided?

A. Again, Dr. Mathiowitz performed those under my supervision, and that was done on all of these, yes.

Q. And did you review the results?

A. Yes.

Q. And did you form some conclusions about the results?

A. Yes.

Q. And generally, what were your conclusions as a result of the infrared testing?

A. These showed clear evidence that there had to be intermixing at a molecular level.

Q. Okay. And what do you mean by "intermixing at a molecular level"?

A. So, maybe I'll draw diagrams with my hands just to help, but if I had chunks, so to speak, of ethylcellulose and HPC, that wouldn't be intermixing at a molecular level, and -- but if I had molecules of HPC and EC, you know, in -- you know, at a molecular level connected together, so the molecules were one right next to each other, that would be intermixing at a molecular level. In other words, the dimensions are very different.

Q. Okay, let's look at some of your data. Would you turn to SPX 2047, please.

A. Yes.

Q. Do you have 2047, sir?

A. Yes.

Q. Will you tell us what's shown on this picture?

A. So, this is an IR, infrared spectrum, of just the ethylcellulose, and to help us, we find a peak, A, that's at about 1740 that we don't see on other things. So, this is a peak that's going to be very distinct for

this part of the fingerprint for the ethylcellulose.

Q. And once again, what is labeled as A in Figure -- in Exhibit 2047, sir?

A. A is this peak that is one peak that's representative of the ethylcellulose that we will not see, for example, when we look at the hydroxypropylcellulose.

Q. Okay.

A. So, it's very representative of the fact that there's ethylcellulose there.

Q. Would you turn to Exhibit SPX 2048, sir.

A. Yes.

Q. What is this data, sir?

A. So, now we get a fingerprint for the HPC, but one thing we noticed is that the A peak, at around 1740, is absent, but a B peak, which was not there for the EC, is there. So, again, we have sort of a characteristic kind of fingerprint for the HPC.

Q. Okay. And would you turn next to Exhibit SPX 2049 and tell us what that is, sir?

A. Yes. So, what was done, I mentioned earlier that the ratio of HPC and EC, there's like a 15 to 1 ratio. So, we simulated that in the IR. We basically took 15 parts of the EC, ground them up to very fine particles, and mixed that with one part of the HPC.

Now, that would not be intermixing at a molecular level, because you'd get these physical chunks. And what we did is we -- and that would be what was asked before, and that's a control. So, we looked at what they'd show, and they do show the A peak and the B peak, which you'd expect, because you basically could envision, if you have part of the EC, you are going to see that, sort of like a couple fingerprints on a glass, you could pick each one out, and we could pick each one out because of the characteristic peaks, even though they're physically mixed.

Q. How does the chart on Exhibit 2049 compare to what you'd expect if the ESI product had distinct and separate layers?

A. That is what you'd expect if there were distinct and separate layers. You'd expect to see distinct and separate peaks, and that's what you see.

Q. Okay. Now, what is behind -- what is the data shown, Exhibit SPX 2050, sir?

A. So, that now is, again, the intermediate, so that's the ethylcellulose-coated crystal. There's no HPC there at all, and you see, as you'd expect, peak A showing up, because that's the characteristic fingerprint, so to speak, for the ethylcellulose.

Q. Okay. And would you now look at Exhibit SPX 2051 and tell us what that data tells you?

A. Right. So, now we looked at the final ESI product, and this was a very different sort of -- you know, I mean, this is very different than any of the other things we saw. Rather than sharp A and B peaks, we see this broad peak. So, clearly something had to happen at a molecular level to cause this to happen. So, the only way that that could happen is there has to be intermixing at a molecular level.

Q. And why aren't the A peak and B peak clear in Exhibit 2050?

A. Because what happens is the way this works is you basically have a different molecular environment, and that's what the IR sees, the different molecular environment is due to the fact that you get intermolecular mixing. That's the only way it can happen.

Q. Now, finally on this subject, would you turn to Exhibit SPX 2054, please?

A. Yes.

Q. Now, would you explain to us what's shown in this comparison?

A. So, this is just looking at the control, and the control is the two substances, the HPC and the EC,

and you see the distinct A and B peaks. That's the top graph, which is in black.

Now, if you take the ESI final product, if there was no intermolecular mixing, you'd expect to see the same thing, those two -- a distinct A peak and a distinct B peak, but rather, we don't see that. We see this broad peak. That's all shown by the red graph on -- the bottom red graph.

So, the point is the ESI product shows a very different fingerprint than what you'd expect if you just had separate and distinct layers.

Q. What conclusion did you draw from the infrared tests about whether or not there were two distinct layers in the ESI product?

A. Well, the infrared studies show that you definitely don't have separate and distinct layers. It shows that you have -- at least you have some mixing at an intermolecular level.

Q. Thank you, sir.

Now, did you also perform calorimetry studies?

A. Yes, we did.

Q. What were those studies, sir?

A. Those are studies where you take a sample, and you heat it, and you increase the heating, so to speak, and then you look where you get a melting, and you ask

the question, how much energy does it take to -- how many -- how much energy does it take to go from a solid say to a liquid?

Q. Okay. And did you perform these calorimetry studies on the ESI samples that you were given?

A. Yes, these were done by Dr. Jeff Hrkach, one of my post-docs, under my supervision.

Q. And did you review the results?

A. Yes.

Q. Okay, very good.

What did you learn from the heat of fusion of the calorimetry studies that you performed?

A. Well, sir, the whole key here is if you have a crystal structure, there will be a certain amount of energy it takes to melt it, to go from a solid to a liquid. So, if there's no intermolecular mixing, you're going to get the same amount of heat all the time. That would be 4.33.

If there is some intermolecular mixing, that would affect sort of the crystal structure, so to speak. It would interrupt it, and it would probably take less energy to melt it. That's what was observed. So, what these studies show is that there had to be some intermolecular mixing since the heat of fusion was changed significantly.

Q. Would you look at demonstrative exhibit SPX 2055, sir.

A. SPX 2055, yes.

Q. And would you explain to us what we're looking at here and what its relevance is to whether or not there's mixing?

A. Yes, this is just showing you that if you take the intermediate, the ethylcellulose-coated potassium chloride crystal, you get a heat of fusion of 4.33. If there was no mixing, intermolecular mixing, when you looked at ESI's product, it also should be 4.33, but there is, because it's lower significantly, and also we have looked at errors on this as well. So, clearly there had to be mixing, because the heat of fusion was lowering.

Q. Did you analyze what the three tests meant together on this question of mixing?

A. Yes, I did.

Q. Did you reach any conclusions with a reasonable degree of scientific certainty as a result of these three tests?

A. Yes, I did.

Q. Would you explain those conclusions for us, please, sir?

A. So, the conclusions show that there's no

evidence that we could find that there was separate and distinct layers, and that taken together with all this data shows is that there is mixing at an intermolecular level.

Q. What level of confidence do you have as a scientist in the conclusion that there's mixing in the ESI coating?

A. Well, a very high degree of confidence, because these were three separate types of tests done many times, with -- so, a very, very high level of confidence.

Q. In connection with the ESI case, did you also look at some dissolution tests that both parties had done?

A. Yes, I did.

Q. And what's a dissolution test, sir?

A. This is looking at how fast something comes out from the -- from the system. In other words, how fast something dissolves out of the -- out of the pill.

Q. And did you dissolve the ESI crystals in some substance?

A. Well, I didn't do these myself.

Q. I'm sorry, thank you.

In the dissolution tests that you reviewed, were the ESI crystals dissolved in a substance?

A. Well, they were all dissolved in -- they were all placed in what are called aqueous water-based solutions.

Q. And did you first look at some data from ESI?

A. It wasn't from ESI. It was from a company they recruited called Ricerca, I guess -- in fact, I don't think they recruited, I think one of their lawyers worked with Ricerca.

Q. Did you look at the Ricerca dissolution tests?

A. Yes.

Q. And what conclusions did you reach from them?

A. Well, there were a number of concerns that we -- I had and my colleagues had in looking at them, because they didn't -- they -- well, first they got one result, which -- where it came out slowly, the thing that they were looking for. So, then they did another test where it came out quickly. So, they got sort of ambiguous results.

And then they also have some other issues where they -- part of how you do these studies are you do standard curves, and they only used one data point on a number of their standard curves, and there are quite a few other issues, too, in them. So, there were concerns about their studies.

Q. Perhaps you better explain just for a moment

what you're looking for in these dissolution studies and what it tells you.

A. Yeah, so, what they're trying to do in the dissolution studies is to generally mimic at some level what might happen in the human body. So, what they're also doing or what one might want to do is simulate that, and there's a procedure called the USP, United States Pharmacopeia, to try to simulate those kinds of things. They didn't do that either, but what you'd be looking at is basically when you do sort of -- put it in a solution, how much comes out over time? Does it come out quickly or does it come out slowly?

Q. How much of what comes out of the -- of what, sir?

A. So, the particular thing that they were looking at in this case in Ricerca was the HPC. They had a theory that if the HPC was not intermixed, it would all come out in a minute, and their reason for saying that, which is probably fair, is that it's a very soluble substance. So, if it's sort of just sitting on the outside as a top coat, everything should come out right away, so that's basically what they were -- that's basically what they were thinking.

Q. Were you able to draw any conclusions from the Ricerca dissolution tests?

A. Not really.

Q. Okay. Would you look at Schering Exhibit 718, SPX 718, sir?

A. Yes.

Q. Would you tell us what this report is, sir?

A. This is a report by Professor Nicholas Peppas at Purdue University looking at dissolution of these capsules.

Q. Did you review this dissolution testing?

A. Yes.

Q. And could you tell us what conclusions you reached based on Dr. Peppas' dissolution testing?

A. So, Dr. Peppas did these studies with many standard curves, and he got the same result every time, and he used the -- you know, a USP procedure, kind of a more gentle shaking. So, the idea was if -- assuming, say, the Ricerca and ESI people were correct, if this -- if this was just a top coat of HPC, no intermixing, it should all come out in a minute. But he saw actually nothing come out after a minute and actually less than 30 percent come out after five minutes, and even after three hours, he still didn't see it all come out.

So, these studies would seem to indicate that, again, there was intermolecular mixing, or rather,

there was certainly no top coat just coming out, because that would have all come out right away.

Q. What conclusions did you draw from the dissolution testing about whether or not there was mixing in the ESI product?

A. Well, again, this is now a fourth piece of evidence done by a totally different test showing that there would be mixing at an intermolecular level.

Q. Okay, and finally, putting all four of the tests together, Dr. Langer, could you tell us what your conclusions were as to whether or not the ESI particle had a mixing in the coating of the EC and the HPC?

A. Right, so taking all four tests together, again, we saw no evidence of separate and distinct layers, and if anything, we do see mixing from these tests.

Q. And what was your conclusion, then, about whether or not there was mixing in the ESI particle?

A. That there was.

MR. LAVELLE: Thank you, sir. No further questions.

JUDGE CHAPPELL: Cross?

MR. NOLAN: Yes, Your Honor.

CROSS EXAMINATION

BY MR. NOLAN:

Q. Good morning, Dr. Langer. How are you?
A. Good morning, fine.
Q. Good to see you again.
A. Nice to see you again, too.
Q. On your direct, you mentioned that you wanted to look at systems very much like what you wanted to check. Is that right?
A. Yes.
Q. But you didn't look at Schering's K-Dur in any of these studies, did you?
A. No.
Q. And you could have done that to -- as a control in your electron microscopic study, right?
A. Yes.
Q. And one would have expected that the Schering tablet would have been mixed at the molecular level, if you will.
A. Probably.
Q. Right?
A. Probably. I didn't study it at all.
Q. You read the patent, right?
A. Many years ago.
Q. And you read the report of Dr. Hopfenberg, right?
A. Yes.

Q. And Dr. Hopfenberg said that the tablet of Schering is mixed, correct?

A. I believe that's true.

Q. So, if you wanted to do a purely objective study with something that was as close to perfectly molecularly mixed as possible, you could have selected the Schering tablet as a control, right?

A. I don't think that's as good a control, if that's what your question was.

Q. You're not denying that it's mixed, right?

A. No, no, many things could be mixed.

Q. And so you didn't look at that for the SEM studies, right?

A. Correct.

Q. And you didn't look at that for the DSC studies, right?

A. Correct.

Q. And you didn't look at it for the FTIR studies, right?

A. That's correct, I felt we had better controls.

Q. And even though you took issue with the Ricerca report, they did use the Schering tablet as a control in the dissolution study, right?

A. Yes.

Q. And when they did it using their procedure,

they found that the HPC in the -- in the ESI tablet came out within one minute, whereas it did not in the Schering tablet, right?

A. No, that's not correct.

Q. There was one test where they used it in relation to water. Is that right?

A. One test.

Q. And they found that it came out -- the HPC came out quickly, within a minute, correct?

A. Well, you're taking the test you like. There are also tests that were done that didn't show that, and there were no standard curves.

Q. This is a yes or no question. They did a test, right, which showed that the HPC came out within one minute, correct?

A. They did -- one of the tests did show that of the many -- of the ones that they did.

Q. And the so-called Schering tablet, which is mixed too at the molecular level, it did not come out within one minute, correct, in that test?

A. In the particular test you're choosing to talk about, yes.

Q. Okay. Well, let's go to more general topics now that we've kind of laid a little bit of background about these highly technical issues and questions of

objectivity.

In terms of your background, the principal work that you did on this matter was about five years ago, right?

A. Yes.

Q. Then you and your associates spent about 50 hours?

A. I think at least 50 hours.

Q. And you maybe spent 20 hours on this before your deposition, right?

A. I'd have to check the exact times. Do you have something that you want to show me? I don't know that it was -- it may have been more than that.

Q. Well, we'll be general about this. In general terms, would you say within the range of 20, 25?

A. It could have been more. Again, it was a long time. I certainly spent the kind of time on it that I would on a scientific paper to make sure that I felt comfortable with the conclusions that I drew.

Q. In this particular -- testifying in this proceeding, you spent maybe 12 hours before your deposition?

A. No, that's not true.

Q. Nicole, could we have the exhibit binders, our exhibit binders?

If I may, Your Honor, I'll approach the witness and approach you with our exhibits?

JUDGE CHAPPELL: You may. Are you going to put it on the ELMO?

MR. NOLAN: We will in a moment, Your Honor. And just before we do this, I realize it's Dr. Langer's own deposition testimony, if we can put this on the ELMO here.

(Pause in the proceedings.)

THE WITNESS: Is there a copy of that I can look at here?

BY MR. NOLAN:

Q. Yes, I'm sorry.

A. Is there a particular --

JUDGE CHAPPELL: You are going to need to zoom in on that, Mr. Nolan.

THE WITNESS: What page?

BY MR. NOLAN:

Q. Just a moment.

If you would turn to page 107, and there's a question there -- actually, it begins on page 106.

A. Yes.

Q. It says, "This is my expert report --" well, "Let's make Exhibit 5 his expert report, which would you identify for the record Exhibit 5, Dr. Langer?

"ANSWER: This is my expert report for this case.

"QUESTION: About how many hours did you spend preparing it?

"ANSWER: Well, I don't know how to evaluate that exactly. This was almost identical to the expert report that I did five years ago, nearly five years ago, so I do not include that or include that time.

"QUESTION: You can answer for before and then answer --

"ANSWER: So as we established earlier, I don't recall exactly how long I spent five years ago, but certainly in excess of fifty hours, maybe considerably more than that, but I don't recall the exact numbers. And on this I think I probably spent reviewing that maybe about twelve hours."

A. Yeah.

Q. Is that correct?

A. Absolutely. But if you read back your question, they were two different questions that you've asked. The one that you asked me just before was how much did I spend time before my deposition. What you asked here is how much time with the report. Those are two very different things. If you want, you can go back and read what you asked me then and compare it to

this. They are not the same. She can do that for you if it helps.

Q. We will leave it as it is.

A. Okay, I just wanted to make sure it was accurate for the record, because those are not the same things. So, I would stand by my answer.

Q. Schering asked you to do these studies, right, Dr. Langer?

A. Schering asked if I would think about a way to do a scientific investigation. They didn't think about the specific studies, but would I do scientific investigation, yes.

Q. They asked you to come here and testify for them as an expert, correct?

A. Yes.

Q. And you didn't publish any scientific reports from this work, correct?

A. Correct.

Q. And you knew it would be used in litigation, right?

A. Sure.

Q. The lawyers from Covington & Burling representing Schering first approached you to do this work, right?

A. Correct.

Q. And they gave you the Micro-K samples for potassium, right?

A. Yes.

Q. They asked you to find out if the EC and the HPC were intermixed at the molecular level?

A. I think really what they asked was -- goes back to what I was asked before, were there separate and distinct layers as ESI contended or not and was there any mixing.

Q. Let's look at page 39.

A. Okay, um-hum.

Q. If it --

A. Yeah, that's just what I said.

Q. On page 39 at line 18, there's a question:

"QUESTION: What did they ask you to do?

"ANSWER: My recollection is they just asked me that if -- they gave me some samples, could we figure out what the truth was, whether they were intermixed at a molecular level."

A. That's correct, or whether they were separate and distinct coatings, and that was the next line. So, it's exactly what I just said. I'm just continuing reading what you said. In other words, basically this says exactly what I just said back to you before.

Q. Did they tell you there was pending litigation?

A. Yes.

Q. And you looked at the '743 patent of Key Pharmaceuticals, right?

A. Looked at it. I don't think I studied it in detail, but I looked at it, yes.

Q. And it's fair to say that -- strike that.

It was always understood that these so-called experiments were to be conducted for the purpose of assisting Schering in its litigation against ESI, right?

A. I think you can say that, sure.

Q. And you wouldn't have gone out on your own to do these tests unless Schering had asked you.

A. Yes, that's correct.

Q. And you were paid to do it?

A. Sure, as I am for all my consulting.

Q. Do you have an up-front payment in order for somebody to retain you as an expert?

A. Sometimes I do. I do now. I don't know if I did then or not, but I do that now, yes.

Q. And what's that?

A. Generally it's $20,000.

Q. Do you know whether it was in this case?

A. You know, I don't know if I did in this case. It may have been before I started doing that. What

happens is I keep getting called by both sides in all these cases, and so I -- I kind of think that was before I did that, but I don't remember for sure, because it was a while ago.

Q. I think if it were me, I would remember $20,000, but you don't recall --

A. Only if people pay me -- again, I do a lot of scientific consulting. I probably consult for over a hundred companies, you know, and in a year or two on all different types of scientific matters, so it's not something that I, you know, know. I think -- I don't think I -- it was at that level then.

Q. In this particular matter, you're being paid $700 an hour?

A. $750 and -- and 50 percent more when I testify.

Q. And with respect to your general qualifications, is it correct to say you're not here today representing the FDA?

A. Of course -- no, I'm not.

Q. And you're not representing your lab at MIT?

A. No, those are all just experiences that I have, of course.

Q. Now, you're a pretty busy person, right?

A. Right.

Q. And you've testified in several different

patent or been an expert in several different patent cases in the last few years?

A. Yes.

Q. And pharmaceutical companies license or sublicense your inventions, correct?

A. Yes.

Q. And it's helpful to your laboratory, isn't it, when you receive money from companies like Schering-Plough?

A. It's -- it's helpful, sure. It doesn't -- I don't think it changes what we do, but it's helpful.

Q. You believe that the biggest reason for the grants that you have gotten is that the private companies want a direct link and license to some patents or work you're doing?

A. That's certainly one of them, yes.

Q. Is that the biggest reason?

A. I think that's probably true.

Q. It's conceivable that a company that hasn't licensed or sublicensed your technology might do so in the future?

A. Sure.

Q. And that would include Schering?

A. Or ESI. Or others.

Q. Um-hum. Now, let's talk about the substance

here.

A. Okay.

Q. Let's talk about the scanning electronic microscopic studies. When this -- when those photographs were taken, you didn't personally look through the SEM, right?

A. That's correct.

Q. You weren't even present when the SEMs were taken.

A. Correct.

Q. They were done at Ms. Mathiowitz's lab at Brown University?

A. Professor Mathiowitz's lab, yes.

Q. And you didn't see how they prepared the sample, did you?

A. It's standard the way she used sputter-coated gold. That's always the way we do it.

Q. You didn't see it firsthand?

A. Not that particular time. I've certainly seen it other times.

Q. And you didn't see how she actually placed it for viewing that day, did she?

A. Not that day. I've seen it other days. These are pretty standard things. It's kind of like after you've taken a photograph with a camera, you know, you

don't necessarily need to -- you know, I would trust you or lots of people to properly do that right. It's the same kind of thing.

Q. Well, thank you, I wouldn't trust me around an SEM --

A. But if you've done it for years, you would.

Q. It was only after the fact that you read these SEMs, correct?

A. That can only be the case for anyone.

Q. And you think at least five people read the SEMs.

A. That's my recollection.

Q. Either your students or other scientists that you normally refer work to?

A. Basically what we did, I think -- again, it was five years ago -- but my recollection was that Edith read them, she had several people on her staff read them, and then I had -- I read them, Jeff Hrkach, who was one of the post-docs in my lab, read them. So, I think at least those five.

Q. And those would be either students or people you have referred work to in the past?

A. People who do this kind of work routinely, yes.

Q. Well, it's a yes or no question. Either they are your students or people you've referred work to if

they're not in some other --

A. I see. Again, I'd have to think about that in each individual case. I don't know enough about the two people that helped Edith.

Q. Some of them were students, correct?

A. They were students or staff members of hers, yes.

Q. And Edith or Professor Mathiowitz is someone you've referred work to in the past, correct?

A. Yes.

Q. And when you refer that work to her, she is paid?

A. Of course.

Q. And what was her fee in this instance?

A. I think it was on the order of $250 an hour. It might have been $300 an hour. I'm not sure.

JUDGE CHAPPELL: Mr. Nolan, let me know when you're at a good breaking point.

MR. NOLAN: Maybe -- it might be fine to break here, Your Honor, because I have a good deal on the SEMs that's technical to go through.

JUDGE CHAPPELL: Okay. Are you finished with that line of questioning?

MR. NOLAN: It's fine, Your Honor.

JUDGE CHAPPELL: All right, why don't we take

our lunch break. We will be in recess until -- we didn't have a morning break. Let's recess until 1:15.

(Whereupon, at 12:10 p.m., a lunch recess was taken.)

AFTERNOON SESSION

(1:15 p.m.)

JUDGE CHAPPELL: Mr. Nolan, you may continue.

MR. NOLAN: Good afternoon, Your Honor.

BY MR. NOLAN:

Q. Good afternoon, Dr. Langer.

A. Good afternoon.

Q. Dr. Langer, we left off with the scanning electronic microscopic slides, right?

A. Yes.

Q. The purpose of the SEM experiment was to see if there was evidence of separate and distinct layers in the ESI tablet of HPC and EC?

A. I think that's fair, yes.

Q. Just so people understand, that HPC is hydroxypropylcellulose?

A. Yes.

Q. And EC is ethylcellulose?

A. Yes, correct.

Q. The two layers, if they existed, would have been about 15 percent of the total weight of a coated crystal?

A. That's correct.

Q. And within that 15 percent, the ratio was one part of HPC to 15 of EC?

A. Roughly, yes.

Q. Okay. And let's take a look, if we could, at your report, which is SPX 713. Do you have that handy? It's in the binder, the Schering binder that Mr. Lavelle gave you.

A. Oh, so the Schering one, okay.

Q. Just take a minute to grab that.

A. So, SPX which?

Q. SPX 713.

A. Yes.

Q. And feel free to make reference to the first page as I'm going through this. I'm going to ask you some questions here.

A. Okay.

Q. Is it fair to say that the first Figure 1 refers to a photograph of the Ethocel?

A. Yes.

Q. So, that's just the Ethocel, right?

A. Yes.

Q. Okay. Now, let's look at Figure 2. It's an SEM micrograph of sample 2. So, the Figure 2 is just an SEM of HPC, right?

A. Yes.

Q. Okay. And let's look at Figure 3. Figure 3 in your summary is an SEM micrograph of the exterior

surface of a microcapsule from sample 3?

A. Figure 3a, is that what you mean?

Q. Figure 3a, I'm sorry.

A. Yes, figure 3a and figure 3b at different magnifications.

Q. So, that's the exterior surface, right?

A. Yes.

Q. You wouldn't expect to see the layering by looking at the exterior surface, would you?

A. Most likely not.

Q. Let's look at Figure 3c. That's a cross-section of sample 3, a sample 3 microcapsule?

A. Yes.

Q. And so that would be the intermediates, right?

A. Yes.

Q. And again -- I should have mentioned this before with respect to Figure 3a, we're looking at something that doesn't have the HPC on it.

A. That's correct.

Q. And that's why you wouldn't have seen the layering.

A. That's right.

Q. Okay.

A. One reason.

Q. Figure 3d is another cross-section, this time

at 2000 magnification, correct?

A. Yes.

Q. And again, that's an intermediate, so there's no HPC on that one either, correct?

A. That's correct.

Q. Figure 4 is an exterior surface view of a microcapsule from sample 4. So, we are dealing now with microcapsules, right?

A. Yes, but to correct what you're saying, Figure 4a and b are the exterior surfaces.

Q. Okay.

A. Yes.

Q. And I was going to get to that, which is Figure 4a, it's a microcapsule, but we're again looking at the exterior surface, right?

A. Figure 4a, and earlier you had said all of Figure 4, so Figure 4a and b are the exterior surface.

Q. Let's talk about all of Figure 4 first.

A. Okay.

Q. Figure 4 are the exterior surface at magnification.

A. Yes.

Q. Would you agree with me that you wouldn't expect to see a layering by looking at the exterior surface for Figure 4?

A. Yes, I would agree with that.

Q. And in Figure 4b, where the magnification is increased to 300, would you agree with me again that by looking at the exterior surface, you would not expect to see the layering?

A. Right, I agree with that.

Q. So, we've gone through the first page, and is it -- it's fair to say that at least on the first page, none of the slides are ones in which you'd expect -- you would be able to see a separation if it existed.

A. Well, a couple points. I mean, I think the answer is yes, but part of what those are done for are to sort of provide kind of controls and references for what you look at, so they're important in terms of making comparisons.

Q. A yes answer will suffice --

A. No, no, and I gave you that yes, but I also just wanted to make clear you understood why we did it.

Q. Moving on, Figure 4c, here we're looking at a cross-section of sample 4 microcapsule, and the magnification is 100 times.

A. Yes.

Q. We're finally -- we're looking at a cross-section. HPC and EC would be present there, correct? I'm not showing the slide, but I'm just

trying to get, you know, an overview of the purpose of this particular slide.

A. Sure.

Q. The -- at that magnification of 100 for this particular object, would you expect to see the layering?

A. If it was there, you might.

Q. You might?

A. Yes. You certainly -- I mean, just for reference, you certainly have no trouble seeing the layering between the EC and the KCl in this, nor do you have that problem on 3c as well.

Q. Just so we're clear, the magnifications used here, on this particular one, it's 100 times. By the end of the study, you're up at times to 2000.

A. That's correct.

Q. So, on the -- all things being equal, this is one of the lowest magnifications in your study, right?

A. Yes.

Q. Okay. Figure 4d is an SEM micrograph of the cross-section of Figure 4c at higher magnification.

A. Yes.

Q. And what was the magnification?

A. 2000.

Q. Okay. Figure 5a is an SEM micrograph of the

exterior surface of a microcapsule from sample 5.

A. That's right.

Q. So, here again we're back to the intermediates, right?

A. Right, 5 will duplicate 3 and 7 will duplicate 5.

Q. Okay. So, just to save people's time here, is it fair to say that for 5a, you're not going to see it no matter what magnification, you're not going to see layering, because it's not physically present?

A. Well, it's physically present. It could -- oh, I see what you're saying, it's not physically present. Yes, that's fair.

Q. And the same goes for 5b?

A. Yeah, those I would view as control samples, absolutely.

Q. Okay. And the same goes for 5c, right?

A. Yeah, these all -- all of 5 and all of 7 and all of 3 are -- you would view as references or controls, so you wouldn't expect to see it.

Q. I'd prefer, since this is a complex subject, to take it one by one so people can --

A. Any way you want, sure.

Q. -- you know, come to their own conclusions about this.

A. That's fine. That's fine.

Q. Figure 5d is a cross-section of Figure 5c, so it's the same, right?

A. Yes.

Q. You're not going to see that there.

So, we're back again on Figure 6a to sample 6. So, we're back to a sample that at least has the potential to be viewed with seeing both layers, right?

A. Yes.

Q. Okay. And Figure 6a is the exterior surface, right?

A. Right.

Q. So, we've already talked about that. You wouldn't expect to see that layering on the exterior surface, right?

A. Right.

Q. And Figure 6b is SEM micrograph of the exterior surface from sample 6 again, right?

A. Yes.

Q. Okay. Figure 6c is an SEM micrograph of a cross-section of sample 6. So, this is one that's at that 100 magnification, so your earlier testimony with another sample was that you might see it.

A. Yeah, and that you certainly do see it with the difference between the KCl and the EC.

Q. But as we mentioned earlier, the KCl is 15 parts to one, correct, of the EC?

A. The EC -- I think you're talking about the HPC.

Q. I mean the EC is --

A. The HPC is less.

Q. Right, okay.

A. Right, I'm just saying that you can visualize things here at the 100 magnification.

Q. The EC is 15 parts to the HPC, which is one?

A. Roughly, roughly.

Q. Okay. Figure 6d is a cross-section of Figure 6c at a higher magnification, and what was the magnification this time?

A. 2000, I think. Yeah, 2000.

Q. Okay. Now, we'll try to move quickly through the remaining. Let's see, Figure 7a, we're back to a microcapsule from sample 7. That's the intermediates, right?

A. That's right.

Q. So, figure 7a, figure 7b, figure 7c and figure 7d would not be ones where you could physically see the separation because there was nothing -- there was no HPC, right?

A. Correct.

Q. I mean, if it's not there, you're not going to

see it, right?

A. I agree with you.

Q. Okay. Now, Figure 8, again we're back to -- we're actually getting a chance to see the compressible, right?

A. Well, this isn't the first time. Figures 4 and 6 --

Q. But I said we're back. This is the third set of compressibles.

A. Yes, right.

Q. Okay. And Figure 8a, this is the exterior surface, right?

A. Right.

Q. So, you wouldn't expect to see it --

A. Right.

Q. -- wouldn't expect to see the separation, right?

A. Right.

Q. And Figure 8b is the exterior surface at a higher magnification.

A. Correct.

Q. Okay. So, we're not going to see it again, even at a higher magnification, you're not going to see it by looking at the outside of this, right?

A. Correct.

Q. And 8c and 8d are the two views of the cross-section, one at the lower magnification?

A. Yes.

Q. And there's one at the higher magnification.

A. Yes.

Q. Okay. So, just so we know where we're at, at this particular point, you have one, two, three, four, five, six, seven, eight, nine, 10, 11, 12, 13, 14, 15, 16, 17, 18, 19, 20, 21, 22, 23, 24, 25, 26 -- 26 views in the SEM, and of those 26, three are at the highest magnification with a cross-section of the microcompressible, right?

A. Of the microcompressible, yes.

Q. Okay. Now, let's talk about what we see and what a person sees when they look at one of these tests, okay?

A. Um-hum, yep.

Q. The SEM slides -- the SEM tests, they are slides that are taken by an electronic microscope that can show the molecular workings of an object, right?

A. Yes.

Q. And you can use various magnifications, right?

A. Yes.

Q. And it gives you a visual picture?

A. Yes.

Q. The SEM test is the only type of test that attempts to visualize whether there is a separation between EC and HPC?

A. It all depends how you define "visualize."

Q. If you could pull out your deposition, turn to page 193, the question on line 6:

"QUESTION: And is it true that the only type of test that visualizes -- that attempts to visualize whether there's a separation or not is the SEMs?

"ANSWER: Right."

A. Right, but you should -- if you keep reading, you keep asking questions about that, and I also discuss that really is just the effect of looking through different windows, so that the FTIR is an atomic visualization. It's really -- so, you're taking that out of context of the deposition. If you want, I can spend some time and try to find those places for you.

Q. That's okay. Your counsel will have an opportunity to --

A. Okay.

Q. -- do that.

A. I just wanted to make it clear to you, I mean, you know there was a dialogue back and forth about that.

Q. Thank you.

At your deposition, I asked you whether you could increase the magnification above 2000.

A. Um-hum, yes.

Q. And you said that you would have to check with Ms. Mathiowitz -- Professor Mathiowitz, right?

A. Correct. I think I said more than that. I think I said it might also affect resolution and things like that, but yes.

Q. So, at least at that time, you weren't even sure what the top magnification is, correct?

A. I don't know if I would phrase it like that. In other words, I just wanted to -- you know, what happens is as you increase magnification, there's issues about resolution at a certain point, and so you want to examine that. It's a question of trade-offs.

Q. As a general proposition, an SEM test at a higher magnification could be more sensitive, correct? It is more sensitive.

A. It depends what you're looking for and what you're looking at, because, you know, if you do higher magnification, you give up portions of the sphere.

THE REPORTER: What was the end of your answer?

THE WITNESS: Of the -- if you increase the magnification, you'll lose your ability to get

resolution on certain portions of the sphere.

JUDGE CHAPPELL: Sir, she wasn't asking you to change your answer; she wants to know what you said.

THE WITNESS: I see, okay, good point.

BY MR. NOLAN:

Q. Just so -- I mean, I think part of the purpose of our being here and talking about this complex subject is to educate, and just so -- not intended with any particular thought other than that, if you look at page 54 of your transcript, I asked you a question. It says:

"QUESTION: Can different magnifications lead to different results?

"ANSWER: It's possible. I don't think they can lead to different results. But, you know, I don't know that they lead to different results. I mean, you might be able to see something better at a higher magnification."

So, you might be able to see something better at a higher magnification, right?

A. Yes, but again, you have to keep reading what that dialogue says. It -- you're taking -- I just don't think it's fair to take it out of context. And I agree with that statement, you might, but you might give things up, which is what I said.

Q. Now, when you gave your report that said that there is some intermixing of EC and HPC, just so that we can be accurate, the ethylcellulose and the hydroxypropylcellulose --

A. You're doing fine.

Q. -- hydroxypropylcellulose.

A. Hydroxypropylcellulose.

Q. You're not saying what degree of uniformity would exist in this mixture.

A. That's correct.

Q. And you're not saying with what degree of depth there is mixing, right?

A. That's correct, too, though -- on this particular study you mean?

Q. Um-hum.

A. The SEM studies you're talking about?

Q. Yes.

A. Yes, you're -- that's correct.

Q. And you can't precisely -- you can't quantify this overlap or mixing, correct?

A. From the SEM studies.

Q. Right.

A. I just want to make sure I understand your questions. If you're limiting those questions from the SEM studies, I'm agreeing. If you're taking all the

studies together, I wouldn't agree. That's all I'm trying to answer.

Q. Let's stop there for now.

A. Yeah, for the SEM studies, I agree with you.

Q. We will get to the other studies.

If we could, Nicole, if we could turn to CX 1681. This is not on. Oh, okay, thanks.

This is, just to identify it for the record, it's a transcript of your testimony in the Key Pharmaceuticals against ESI Lederle matter dated 5/6/97.

A. Do I have a copy of that here, too, to look at or --

Q. She is going to -- Nicole is going to bring it up on the screen for you.

A. Okay.

MS. GORHAM: You actually do have a copy in your binder.

THE WITNESS: Okay, can you tell me which --

MS. GORHAM: CX 1681.

THE WITNESS: So, this is the other book, CX 1681, okay. Okay.

BY MR. NOLAN:

Q. If you could turn to page 17.

A. Seventeen, okay.

Q. Right. You were asked a question, and the question is:

"QUESTION: What is your understanding of the degree, if any, to which the hydroxypropylcellulose is mixed at the molecular level, or intermixed at the molecular level?

"ANSWER: As I said, I see some mixing at the intermolecular level.

"QUESTION: As far as you are concerned, it may be a monomolecular layer mixture of HPC and EC?

"ANSWER: I wouldn't think so. Again, I saw no evidence -- I mean, basically, we saw significant changes both with the DSC and the FTIR. I would doubt that, very much, that we'd see it if it was a monomolecular layer.

"QUESTION: Well, to what extent of the ethylcellulose do you think there's a mixing of the HPC?

"ANSWER: I can't say. All I can -- what I have to keep coming back to is the issue about separate and distinct layers, and that I couldn't find separate and distinct layers of ethylcellulose and hydroxypropylcellulose."

Continuing with this line on page 19, at line 17, there's a question:

"QUESTION: I'm trying to find out whether you can give me, based on your examination and all of your experience, the extent to which you believe the hydroxypropylcellulose is intermixed at the molecular layer with ethylcellulose?

"ANSWER: The extent.

"QUESTION: The extent.

"ANSWER: I think it's hard to be quantitative. I think you can say either yes, it is, or no, it isn't, but it's hard to give a quantitative answer to that."

My question is, you said that then, right?

A. Yes.

Q. And the ESI lawyers knew that you wouldn't be able to quantitate the extent of the mixing, right?

A. Well, but we did, we did later -- additional experiments were done, as was gone over in direct, the dissolution experiments.

Q. I'm referring to this particular --

A. Okay, so your point -- you're talking about this point in time with just these experiments?

Q. Right.

A. Yeah, I agree with that, at this point in time with these experiments, what I said was exactly right.

Q. And so you knew that at least with respect to the SEM, the DSC and the FTIR, you would not be able to

quantitate what degree of mixing there was, right?

A. Right, if you look at my report, it basically says that there's mixing, and there is certainly no evidence at all of separate and distinct layers. But that's all I said, I didn't quantitate it, and I felt that was appropriate given those tests and still do.

Q. But in the context of what people knew at that time and the litigation that was going on, it's fair to say that ESI's lawyers heard you say that you wouldn't be able to quantitate the degree of mixing, right?

A. In May, but then there was another deposition later where we did quantitate it, and they heard that, too.

Q. At least at this point, with these particular studies, right?

A. Right, in May; however, I think there was another one in September, but that's correct. I just want to make sure you're giving the complete -- I want to give you a complete answer. I mean, you're asking me a question, so this was one deposition. There were two. They heard them both.

Q. And at your deposition with me, you told me, didn't you, that you can't say that it's -- the maximum you can say is that it might be 50 percent?

A. I said conservatively, 50 percent was what I

felt comfortable with, yeah.

Q. Fifty percent.

A. Yeah, conservatively.

Q. Your report on the dissolution refers to 0.5, correct?

A. That's right.

Q. So, that's 50 percent?

A. That's right, exactly. No, and I think all that's exact. I think all that's correct.

Q. So, in -- on page 22, continuing with this just for a moment, you were asked a question, Dr. Langer, where the ESI lawyer is saying:

"QUESTION: And if, presently, you have some ideas as to how you determine this quantitatively, I have'd like to hear that. If you don't presently have any ideas, just say so, and we can move on.

"ANSWER: Well, but it's not that simple. I mean, you're trying to make something sound simple, and science doesn't work that way, necessarily. And so --" and you continue on.

A. Right.

Q. It's fair to say that when the ESI lawyers were taking your deposition then that they asked you to quantify with respect to these three tests which were major tests that supposedly became part of your initial

report, FTIR, DSC and SEM, and let me -- let me rephrase the question.

A. Okay.

Q. They asked you at that time about the three tests that had already been done.

A. The -- which lawyers now?

Q. The ESI lawyers.

A. Right, right.

Q. Asked you if you could quantify the extent of mixing, referring to your SEM test, your DSC test and the FTIR test, correct?

A. Right.

Q. And you couldn't at that point.

A. I could just say --

Q. For those tests.

A. -- I could just say there was mixing.

Q. And you still can't, looking at those tests alone, you still can't say any particular number, correct?

A. You mean now we're excluding the other tests I talked about this morning, the dissolution tests?

Q. Yes, relying individually on these.

A. On these three, all that I've shown in my opinion is what I just said, no evidence of separate and distinct layers, but to the contrary that there's

mixing.

Q. You just detect some mixing, correct?

A. Well, significantly, because you see these very significant changes on the separate tests, like the DSC and the FTIR, and in addition, with the scanning electron micrographs, you see no evidence of separate and distinct layers.

Q. Well --

A. So, I guess I felt that was very compelling.

Q. Well, let's take a look at the slides themselves.

A. Sure. Do you want me to pull up a different book or what's the best way to do this?

Q. Just a moment. If we could, Nicole, look at CX 1679, and if we could refer to Figure 8d.

A. Okay.

Q. Which is on -- well, it's a few pages in.

A. Um-hum, okay.

Q. When I showed you this particular slide, and it may be -- let's just see -- we'll also look at it afterwards using the ELMO, but just for a moment --

A. What's -- using the ELMO, what's --

Q. The ELMO, this is the ELMO (indicating).

A. Oh, I see.

Q. And just -- why don't we just switch for a

second, then we'll come back.

When we had our deposition with you, Dr. Langer, you said that you didn't think these were the greatest slides for clarity, right?

A. These particular ones. The original ones were.

Q. But those aren't here today, right?

A. I don't think so.

Q. You don't even know where they are.

A. Well, I gave -- we gave everything we did to the people -- you know, the lawyers originally.

Q. Looking at Figure 8d from the SEM study --

A. Yes.

Q. -- I showed it to you during deposition, and let me just ask you, you saw something different optically between -- switching back, that there is a line that I drew, a 1 and a 2 and a 3.

A. Yes.

Q. The 1 is the potassium chloride, right?

A. Right.

Q. The 2 and the 3, I asked you if you saw something different between the 2 and the 3.

A. Yes.

Q. The 2 and the 3 being that there's a line that I drew to the right of Figure 8d, right?

A. Right.

Q. And you said that you saw something different optically, correct?

A. I'd want to hear the context, I mean, that you're talking about. If you want, I'll take a look at what I said.

Q. Let me just continue with this and then we'll look at your testimony.

A. Okay, okay.

Q. I'll ask you the questions, and --

A. That's fine.

Q. -- hopefully you'll -- I'm sure you'll give the best testimony you know.

A. Sure.

Q. You see something differently optically between 2 and 3, correct?

A. There's, you know, more granular appearance in part of it on the right-hand side if that's what you're saying.

Q. And you see a bit of a contrast between the area marked 2 and 3?

A. Yeah, I think that's fair. I think there's an optical contrast. That doesn't necessarily mean they're different, but there is an optical contrast. I think that's fair.

Q. And this sample was one that had been sliced

for a cross-section, right?

A. Yes.

Q. In your original depo, did you admit that -- or you said, you gave testimony that, "you may get a certain angle depending on how the razor comes down on it"?

A. I may have said something like that.

Q. And the samples that you took here were samples that were sliced without any freezing, right?

A. That's correct.

Q. It's possible that somebody, another scientist who wanted to do this same study, might freeze the sample to protect it while it's being sliced?

A. I think -- well, we actually looked at that as well. Freezing it, depending on the temperature you do it, will crack it. I mean, that's not really a very good procedure in microscopy, unless you cut incredibly thin sections. We did that as well. We didn't see anything there either.

Q. The ESI lawyers did SEMs where they freezed the cross-section?

A. I think they put it in liquid nitrogen, which will crack it, yes.

Q. Now, just coming back to a point of comparison and control, no SEMs -- you never took any SEMs of

Key's product, correct?

A. That's right.

Q. Which everyone concedes is a mixture.

A. Yes, though our comparison kept being this against the one without the coating. That was the easiest thing to visualize, because they look so similar.

Q. At the time of the -- your original deposition in the ESI case, did the ESI lawyers put these SEMs in front of you?

A. My SEMs?

Q. Yes.

A. They very well may have, yes.

Q. And in one of them, did they ask you if there was a lighter area on top?

A. They certainly could have.

Q. Which -- whether or not you'd see a layering?

A. I'm not clear on the question you're asking.

Q. Okay. Well, let's just go back to your deposition transcript in the original case --

A. Okay, if you refer me --

Q. -- which is CX 1681.

A. Yes.

Q. If you would turn to page 133, if you could, Nicole. So, there -- and I'm sorry, we'll have to come

back to the particular slide in a minute, but they are looking -- just for the record, I'll say that they're looking at slide 6d.

A. Um-hum, yes.

Q. And let's just switch for just one second -- well, let's -- I'm sorry, let's continue with this, where it says -- there's a question on 133, we're on line 5, it says:

"QUESTION: Right. I'm just trying to say, isn't this a lighter area about maybe, say, one thickness compared to about 10 or 15 thicknesses of the darker area below it?"

A. Um-hum, yes.

Q. "ANSWER: And what I'm trying to say is really to interpret that.

"QUESTION: Let me do it step by step.

"You're just saying you can't see a coating in 6d?

"ANSWER: That's right, that's any different from my reference in 5d," and you continue on.

A. Yes.

Q. And it continues to page 134 where there's a question, "But you don't see a differentiation in 5d that you see in 6d, right?

"ANSWER: I think you see the same minor

change, which I believe has to do with light reflecting."

So, before we go to the slides, I mean, is it fair to say that at the time of the original litigation that it's quite likely that you would have given one view as to what these slides said, for instance, here 6d, and ESI was poised to provide a different view?

MR. LAVELLE: Objection, Your Honor, speculation.

MR. NOLAN: I'm -- I'm requesting the state of mind of this witness in terms of what he knew, that he knew that ESI lawyers were going to be putting on experts, a battle of the experts, and they were going to be looking at slides that were not necessarily the best in the world, and the same slide that you, Dr. Langer, would have said you don't see a layer, some other expert would have said, well, I see it, or even in my earlier example, where you said you thought you saw something, so it's purely for the purpose of showing --

JUDGE CHAPPELL: Excuse me.

MR. NOLAN: -- that this was a battle. It's not solved by one report.

MR. LAVELLE: Your Honor, objection. It's speculation, it's argumentative, it's not even really

proper impeachment. All he's doing is -- he's not asking him questions to impeach him. He's just reading transcripts and arguing about them. I think the question's improper and the line is improper.

JUDGE CHAPPELL: I'll allow it. The objection's overruled.

BY MR. NOLAN:

Q. Let's look at slide 6 --

A. Do I answer it, then, or what do I do?

JUDGE CHAPPELL: You can have him restate it or you can have the court reporter read back the question.

(The record was read as follows:)

"QUESTION: So, before we go to the slides, I mean, is it fair to say that at the time of the original litigation that it's quite likely that you would have given one view as to what these slides said, for instance, here 6d, and ESI was poised to provide a different view?"

THE WITNESS: Yeah, I really don't know, and I don't think so. I mean, my sense would be the following: We had five people read them, and I think they were very clear. I think that ESI, Harold Hopfenberg, was the one person they had who really had no experience reading micrographs, as far as I know, and I think he would have been hard-pressed to do this.

I'd add, we can go check this in my transcript, that I think we personally looked at 5d and thought that there was a layer there, and, of course, 5d is one that has no layer, because as you correctly pointed out, it can't. So, I think the point that I kept making over and over and that all of our people did is we kept comparing the odd ones to the even ones, and I think when any reasonable person looks at the odd ones compared to the even ones, it's really hard to tell that there's anything different.

BY MR. NOLAN:

Q. Let's look at Figure 6d, if we could, Nicole.

Do you see that area at the top of Figure 6d?

A. Yes.

Q. The lighter area?

A. Yes.

Q. That's what the ESI counsel was questioning you about?

A. Yes.

Q. And he was asking you isn't that a separate layer?

A. I think that's what he was asking, yes.

Q. And he asked it in the context of looking at 15 of EC to one of HPC?

A. Yes.

Q. Let's talk about the other tests.
A. Do you want me to compare -- just stop there? Okay, that's fine.
Q. Let's move on to talk about the other tests.
A. Sure.
Q. The FTIR test, Dr. Langer, is designed to show changes at the molecular level, to show molecular bond stretching, right?
A. Well, stretching and rotation, things like that.
Q. Your reason for doing the test was to see if there was a change when you looked at EC versus looking at EC and HPC together?
A. Yes.
Q. And just so we're clear, the control that you had, you ground up EC and HPC?
A. There's several controls, right, there's --
Q. Well, one of the controls.
A. Yes, yes.
Q. But that's not an accurate depiction of exactly how the EC and the HPC is on a tablet, right?
A. Similar dimensions and similar -- you know, from the standpoint of the IR, I'd say it probably is.
Q. But it's not grounded up when you're looking at it on the tablet.

A. But the dimensions are comparable, and to the IR -- that's how you do IRs. You grind them up.

Q. In the FTIR test, the EC and the HPC have their respective peaks, correct?

A. Yes.

Q. But you have no idea what those particular peaks represent, other than they occur, right?

A. Well, we know that they're different bond stretchings and bond rotations. We don't know -- if you're asking do I know exactly, you know, is it a COO stretch or something else, we didn't take it that far. What we do know is that there's stretching and rotations.

Q. You don't know what causes their height, right?

A. Well, I think we know what -- we know it's what I said. We know it's some type of stretching and some type of rotation. We didn't identify the precise chemical mechanism if that's helpful.

Q. Some type of something.

A. If you want to look at it that way.

Q. You don't know what the bond or anything else correlates with, correct?

A. I don't understand the question.

Q. When you look at the peaks, and I asked you -- I've asked you what the peaks represent, you don't know

what particular bond, how that particular molecular bond is shaped, right?

A. So, if the question is did we -- do we know exactly what chemical bond stretching or rotation it is, the answer would be no, we just know that it is a unique stretching or rotation.

Q. And in your work, you didn't understand -- you didn't attempt to understand what causes a peak, right?

A. We didn't take it that far, correct, beyond what I said.

Q. You didn't understand why there was a broadening in the sense other than that you're inferring that there's some mixing, correct?

A. Well, you know when you get such a dramatic change in fingerprint, so to speak, or in bond -- or in the peak structure that it has to have a major change on either the bond rotation or stretching.

Q. When you did this test, you didn't have any known parameters related to the broadening to conclude whether there was intermixing, right?

A. I don't understand the question.

Q. Well, let's go to your transcript again --

A. Which --

Q. -- CX 1681.

A. Um-hum, okay.

Q. Page -- I think 165.

A. Okay. All right.

Q. Okay, a couple of questions, I'll read a portion of the questions and answers and then ask you some questions.

A. Sure.

Q. "QUESTION: Now, would a change in peak heights be an indication of intermixing?

"ANSWER: I'm not sure. What I guess I'm trying to say is that peak broadening, you know, in essence, new peak, so to speak, to me, that's a clear indication of intermixing. That's what we've seen.

"QUESTION: And my question was, would changes in peak height be an indication of intermixing?

"ANSWER: Right, and I said I guess I'd want to think about that more, study that further, to give you an answer about that.

"QUESTION: Now, with regard to peak broadening, are there any parameters you look for with regard to the extent of broadening to find out or to conclude whether there is intermixing?

"ANSWER: I haven't looked at that so far, you know. There may be. I'd want to study that further. To me, it was clear-cut --"

A. Very clear-ought.

Q. "-- very clear-cut. I mean, you just looked at it and there was very substantial broadening, whereas in the other cases, there was none."

Again, trying to bring -- we can't bring the original case back to life. That judge isn't here, that jury isn't -- or there wouldn't have been a jury, but those lawyers are not necessarily here, but the question is, when you -- when you look at this and your answers where you said I'm not sure, isn't it fair to say that the EC -- the EC -- the ESI lawyers, not ethylcellulose, the ESI lawyers would have pounced on that at trial, that -- in terms of -- and I'm asking you this question in terms of what you knew and what Schering employees knew.

They knew that you would be testifying in some areas that you were uncertain, and this is -- correct?

MR. LAVELLE: Objection, Your Honor. It's hard to understand and completely argumentative.

MR. NOLAN: Your Honor --

JUDGE CHAPPELL: It did contain more than one question, so it's at least a compound question, so you'll need to try again, Mr. Nolan.

BY MR. NOLAN:

Q. My point is a simple one, which is in the context of this proceeding, in trying to divine

whatever it is that the lawyers at Schering and Schering itself must have thought as they -- as they entered a settlement here, is it's fair to say that both sides knew that there were important things in your report that you didn't know the answer to; you weren't sure.

MR. LAVELLE: Objection, Your Honor.

THE WITNESS: Do I --

JUDGE CHAPPELL: Basis?

MR. LAVELLE: Speculation, asking him what other people knew.

JUDGE CHAPPELL: Overruled. If he knows, he can answer.

THE WITNESS: I can only give you my assessment of something like this, and it's actually the same thing I said at the deposition. A couple points. Point one, as you know, any scientific investigation, I can't think of any in history where there's not more question -- where there are things that you don't know. There's always things that you don't know. That's true for all the papers I've written, and it goes back through scientific history.

So, the fact that they could ask me questions that I -- about an investigation and I don't know some of the answers, that makes a lot of sense, but it

doesn't change the fact, and I think this is what's so key, that when you have a fingerprint, which we did, and you see that huge peak broadening, which we did, that whole new peak, that's unequivocal. I mean, that's so unequivocal that anybody really knows that -- that you've got a big change.

So, the only thing that they could do, it seems to me, is to try to make points like this. And I would agree, sure, there's always going to be points in any scientific investigation that I won't know the answer to, but it's irrelevant. I mean, the fact is, you see this fingerprint change. It's as simple as that.

BY MR. NOLAN:

Q. The word "parameter" relates to a criteria for a judgment, correct?

A. I -- I'm not sure.

Q. In common parlance -- when you have a parameter, that's a criteria for judging whether something fits or doesn't fit, whether -- for evaluating something. Would you agree with that?

A. Just having -- I mean, maybe it's -- maybe I'm becoming dense -- I'm just not sure what you're asking exactly.

Q. Well, when the ESI lawyer asked you if there were any parameters that you looked for with regard to

the extent of the broadening --

A. Oh, I see.

Q. -- and you said I haven't looked into that thus far, isn't it fair to say that you're saying that you don't have any parameters that are known?

A. Well, I mean, maybe put it this way, I mean again, just to give you an analogy. If I get a fingerprint and it's different from another fingerprint, to me that tells me that there's two different things. Do I know every single detail about why those fingerprints occur? Maybe not. And I think, you know, maybe that's where the parameter things come in, but it still makes it very easy for me to identify that those two fingerprints are very different or those two pieces of DNA are very different. You know, I don't need to understand every single parameter to know -- to see a difference.

Q. Well, if we're talking about mixing, it would be helpful, wouldn't it, to have a parameter for mixing?

A. But we do. We have the absolute real thing, where we saw the distinct peak A and the distinct peak B when they weren't molecularly mixed, and now you see this nice, wide, broad peak when they are molecularly mixed in the ESI system. I mean, there's no other

explanation for that.

Q. Let's move on to the DSC test.

A. Sure.

Q. The DSC test is designed to show change in melting behavior, right?

A. Yes.

Q. And your theory would be that a change in melting behavior is probably attributable to mixing at the molecular level of HPC and EC.

A. I don't think that's a theory, but I would agree with what you said.

Q. Well, you went into the experiment with a theory, did you not?

A. I wouldn't call that a theory. I think that a theory -- I think basically the way I look at it is if there's something that would interrupt a crystal structure, that's a -- that will change melting. Everyone knows that. That's state of the art. That's not theory. The question is what happens to the ESI product. That could be -- so, I would say we have a hypothesis.

Q. And by the way, when you say "what happens to the ESI product," you didn't do the same test, did you, with Schering's product to see if you'd get the same result?

A. That would have been difficult to do, because the Schering product didn't have an intermediate in the same sense.

Q. The Schering product is a mixture, right?

A. Yes.

Q. So, if you wanted to show what a mixture would look like under a DSC test or an FTIR test, you could have very well have done the same test using the Schering product as a control, right?

A. It wouldn't have been a good control. If you want me to, I'll explain.

Q. No, I'm asking you, you could have used that, because it's a mix, correct?

A. No, because you have to go to the experiment. With the DSC, the reason we were able to make those conclusions is because you look at the -- at the intermediate, which you don't have in the Schering product. So, you use the intermediate as a basis, and you ask the question, does it stay the same or does it go down? You can't ask that question with the Schering product.

Q. You could have ground up EC and compared EC to the result in the Schering product -- in the overall Schering K-Dur capsule, right, as a control?

A. That's an inappropriate control. Now we're

really going way beyond -- I mean, not that that doesn't -- now we're taking something that's very different.

Q. You could have even seen if the values you obtained in the FTIR test or the DSC test with the final Schering product were similar to the ESI product, considering that the point is to show they're both mixes.

A. Well, but they could be very different if there were different other components in, which there were, like stearates and so forth. I mean, what you're saying just -- I mean, again, it doesn't make sense what you're saying.

Q. So, they could be very different, couldn't they?

A. The melting temperatures could be different, but that doesn't mean they wouldn't be mixed, if you understand what I'm saying.

Q. Now, is it true that processing conditions can change the crystallinity of the EC or ethylcellulose?

A. It's possible. We actually looked at that.

Q. And is it true that a solvent can change the EC crystallinity?

A. It's possible -- well, the crystallinity -- it's possible, but we looked at that also.

Q. You're aware of the term "artifact"?
A. Sure.
Q. What's an artifact, Dr. Langer?
A. It's something that gives you a result which probably isn't real.
Q. And as a scientist, you wouldn't want an artifact to come into play, right?
A. Exactly.
Q. Because they bias results?
A. Well, they give you wrong results.
Q. Um-hum. And the way that artifacts are ruled out is to use controls in your experiments?
A. And to do additional -- to do controls and to do additional experiments that might help you lock on the very issues you just raised. We did experiments to check those things.
Q. Now, on all these tests, you never used the Schering capsule as a control, correct?
A. Right, didn't think it was appropriate.
Q. That would have been pretty easy to do, wouldn't it?
A. It would have been easy, but inappropriate.
Q. And you would have had plenty of access to it.
A. But why -- again, if I didn't think it was an experiment that made sense, why would I do it? I could

have had access to all kinds of things.

Q. If it turned out to be different than the competing ESI tablet -- strike that.

Now, briefly, going back to the FTIR and DSC tests, there's some other important areas that go to I think how we should look at these tests, what context they were done in, and so I'd like to go through that briefly with you now.

A. Sure.

Q. At the time that you did these tests, you hadn't looked into with any detail how a water-soluble polymer applied to a layer of a water-insoluble polymer would interpenetrate, correct?

A. I think that's -- certainly not in a circumstance exactly like this.

Q. Were you --

A. Dr. Banker may have, but I may not have.

Q. When the DSC and the FTIR experiments were done, you had done very little, if any, experiments to look at the interface of one polymer applied to another, correct?

A. Yes, that's correct.

Q. And you didn't know of anyone who had used DSC to examine the molecular mixing or intermixing at the molecular level of two polymers, right?

A. That's true.

Q. And you had not done DSC much, if at all, looking at the interface of one polymer on another, correct?

A. We did lots of DSC, just not with that particular example.

Q. Not with looking at the interface of one polymer on another, right?

A. Right, as I said, we have done lots of DSCs, just not in that particular example.

Q. And you haven't done a literature search on whether others have used DSC to examine the molecular mixing of two polymers, right?

A. That's true, it's straightforward.

Q. You concluded that -- strike that.

With respect to the dissolution test, those tests were done by a Dr. Nicholas Peppas?

A. That's correct.

Q. And he runs his own lab with his wife?

A. He has his own lab at Purdue University. His wife has a -- kind of a contract company called Viogel (phonetic), so they're kind of separate, but obviously they're located together.

Q. Dr. Langer, does Dr. Peppas teach a course with you?

A. I teach a course that involves him and about seven other people, yes.

Q. And you didn't even provide off-site supervision for those tests, right?

A. I didn't see any need to.

Q. You merely -- you didn't -- you didn't provide off-site --

A. These tests are so routine, I mean, they don't require off-site supervision.

Q. That's just a yes or no answer. You did or you didn't.

A. No, I didn't.

Q. Okay. You merely analyzed the results, right?

A. Correct.

Q. With respect to the FTIR test, those tests were done by Edith Mathiowitz?

A. Correct, under my supervision.

Q. And you don't recall if you were present when those tests were done, right?

A. Correct.

Q. So, the primary -- so, the primary sources of information that you now testified to are primarily based on experiments that others did, right?

A. Well, I was involved in all of -- many, many aspects of those experiments, so I wouldn't agree with

that. If you're saying did I do them with my hands, no, but I was involved in the conception of the experiments, the design of the experiments, the analysis of the experiments, the training of the people who did the experiments, so I feel I was very involved in them.

Q. For the SEMs, you got one set of ESI's Micro-K -- or three sets, right?

A. Correct.

Q. You don't know how the Covington lawyers got it?

A. I don't know.

Q. You don't know who had it before you received it?

A. That's fair.

Q. You only analyzed that -- those three sets, right?

A. That's correct.

Q. So, you didn't take a statistical sample of, you know, take a hundred tablets in and then somehow, you know, randomly pick out which ones you were going to look at?

A. Well, we took three different batches, and we took many different samples out of those batches. So, we probably did do hundreds.

Q. You didn't visit the ESI Lederle plant, did you?
A. Correct.
Q. You didn't see the manufacturing process?
A. No.
Q. You didn't inspect the product?
A. What do you mean?
Q. There.
A. Oh, there, no.
Q. And you didn't ask the manufacturing people any questions about how they made it, right?
A. That's all correct.
Q. You didn't review any of the testimony of the ESI executives about the process of manufacturing the pill?
A. That's correct.
Q. Now, you've mentioned Dr. Hopfenberg, correct?
A. Correct.
Q. And he was the expert witness on the other side.
A. That's correct.
Q. Nicole, if we could turn to CX 441, the expert report of Dr. Harold Hopfenberg -- and just so that it's clear, this report, Your Honor, is dated February 22nd, 1997, signed by Dr. Hopfenberg. It's in the

matter of Key Pharmaceuticals versus ESI Lederle.

If we could turn, Nicole, to ESI EXP 000737.

A. Is there a page I should look at?

Q. If you would turn in -- use those Bates numbers at the bottom of the --

A. Okay.

Q. -- it's 737.

A. Okay.

JUDGE CHAPPELL: It should be about page 22.

THE WITNESS: That's his CV, right?

BY MR. NOLAN:

Q. Yes.

A. Oh, okay.

Q. Do you recognize that as Dr. Hopfenberg's CV?

A. Sure.

Q. So, I take it you don't disagree that he has a Ph.D. in chemical engineering from MIT?

A. I don't disagree with that, no.

Q. And you don't find any particular faults with his CV?

A. Well, actually, since you asked that question, I think we did analyze it. I think my post-doc had more patents than he did, and I don't think he published hardly anything in this area at all and hardly had -- and then very few publications over the

last decade. He's mostly done administrative stuff. So, my answer is that he really had minimal qualifications for doing this type of analysis.

Q. Is it true that he's been the head of the Department of Chemical Engineering at North Carolina State?

A. He was at one point, yes.

Q. He was, between '80 and '87?

A. Yes. I think then he became athletic director or something like that, as I recall. It may say that.

Q. It says Department of Chemical Engineering, and he was also --

A. Right.

Q. -- just -- I don't want to go through all his qualifications. I just want to --

A. Yeah, the athletic director was between '89 and '90.

Q. He was the Camille Dreyfus Professor of Chemical Engineering?

A. Yes.

Q. Okay. So, again, you know, I'm not asking you this just to -- we've heard a lot of people pointing to, well, is this in the document and so forth. I'm really going for trying to understand what was happening at that time. So, it's fair to say, ESI had

an expert, right?

A. Yes.

Q. And that expert had a Ph.D.?

A. Yes.

Q. And he was prepared to testify, like you were prepared to testify, right, for ESI in this case?

A. I can't deny that. I'm sure he was prepared to testify. I think he did testify at the Markman hearing, didn't he?

Q. He testified at the Markman hearing, and you didn't, right?

A. Dr. Banker I believe did, but I didn't, no, I did experiments.

Q. Because in the prior litigation -- in the Markman hearing, the critical issue was claim interpretation, right?

A. I -- I wasn't there. I don't know.

Q. Just going to -- if we could go to Bates number 725 --

A. I'm sorry, page 7 --

Q. 725.

A. Oh, of his -- all right, I got it.

Q. Right.

A. Sure. Okay.

Q. Again, where it refers to the differences

between Key's claimed invention and ESI Lederle's Micro-K 20 are substantial, is it fair to say that his expert opinion differed from yours?

A. I didn't address that issue. I just really wanted to look at the -- so, you should probably ask Dr. Banker that question, but what I just tried to do is one simple thing, is to try to do experiments to look at whether there were separate and distinct layers or whether there was mixing. So, I -- really, my involvement and my goal was to simply look at this as a scientist and to try to make an experimental assessment. I didn't get into the -- this particular point.

Q. Well, let's break it into two parts.

A. Sure.

Q. Is it fair to say that with respect to the patent claim interpretation, Dr. Hopfenberg's conclusion was adverse to Schering?

A. I assume that it was. I really didn't approach it that way, and, you know, like I said, I was looking at the experimental issue. I assume from everything that I've seen that it would be.

Q. And is it also fair to say, then, because we'll get into this a little bit more, that with respect to your experiments, those are not necessarily targeted to

a particular look-see at the patent? It could be that you did your experiments -- well, we'll strike that. I'll just ask you that your experiments were not on the face of it directly related to the patent, the '743 patent.

A. You'll have to ask others about that. My understanding was there was an issue about whether -- or there could have been an issue about whether there could have been separate and distinct layers or whether there could have been mixing. So, my goal was to address that issue scientifically.

Q. That issue?

A. That issue.

Q. Okay, let's move on to CX 444.

Before I do, actually, let me just mention with respect to CX 441, complaint counsel would like to offer this into evidence, Your Honor, on the grounds -- several grounds. One is that Dr. Hopfenberg signed this under oath. He testified in the previous matter. There's sufficient grounds of reliability. We've given notice to the other side that it would be in our CX -- CXs in this case.

JUDGE CHAPPELL: Objection?

MR. LAVELLE: Your Honor, I'm not sure if it's on our list. I mean, Dr. Hopfenberg's not here, I

can't cross examine him and -- I'm not sure when we received notice about this, but it seems to me it's hearsay, an out-of-court statement, and that we can't cross examine Dr. Hopfenberg, so I object, subject to I haven't been able to check if it's on our list.

MR. NOLAN: Your Honor, we would just say that Dr. Hopfenberg gave this statement under situation of sufficient indicia of reliability, under the catch-all exception to the hearsay rule, it should be allowed in. They have the deposition of Dr. Hopfenberg. They asked questions of him in the previous -- Schering did in the previous litigation. If they want to put in excerpts, you know, revealing what they believe are omissions, that's fine, but we think that this would be useful and relevant to you in your analysis.

JUDGE CHAPPELL: I believe he said he was objecting until he could find out if you had given him notice of it. So, why don't you withhold your offer at this time, Counselor.

MR. NOLAN: Okay.

JUDGE CHAPPELL: Move along, thank you.

MR. NOLAN: Okay.

BY MR. NOLAN:

Q. The CX 444 is -- if we could look at that, do you recognize this as the surrebuttal expert report of

Harold Hopfenberg, Dr. Langer?

A. Yes.

Q. And was -- in looking at paragraph 2, the second sentence down, it reads, "Additional data --" Nicole, if you could blow that up, the second sentence, "Additional data."

A. Right.

Q. Okay, "Additional data now show that ESI Lederle's hydroxypropylcellulose (HPC) binder is quickly removed in water from the ESI Micro-K 20 microcapsules, whereas, under the same conditions, no HPC is removed from Key's controlled release coating material."

Is the theoretical point there, let's just start with the theoretical point, if the HPC, which is water-soluble, was removed quickly from the tablet, the ESI tablet, that the theory here would be that it's not intermixed, right?

A. Correct.

Q. And so -- and I'm just asking you what Dr. Hopfenberg's assertion would have been, that he would have testified in this proceeding, presumably, that the HPC binder layer was quickly removed in the ESI Micro-K, but it was not removed quickly from Key's. So, was -- is it fair to say that the inference that he

wanted or the conclusion he wanted to draw there is that in the ESI tablet, Dr. Langer, it was not intermixed, but in the Key tablet, because it didn't remove, it must have been intermixed?

MR. LAVELLE: Objection, speculation, Your Honor.

MR. NOLAN: I --

JUDGE CHAPPELL: Well, I am going to sustain the objection. It's speculative, but also it's a compound question and it's vague. Restate your question.

BY MR. NOLAN:

Q. Dr. Hopfenberg -- thank you, Your Honor.

Dr. Hopfenberg was asserting that he found in a test that the HPC was removed from the ESI tablet in a manner that one would expect if there were two separate layers, correct?

MR. LAVELLE: Same objection, Your Honor.

JUDGE CHAPPELL: Well, if he -- I'll sustain it. If you're asking this witness if he knows of it, if he agrees or disagrees, that's fine, but the way you've asked him the question, you're asking him to speculate.

BY MR. NOLAN:

Q. Do you agree that that -- that Dr. Hopfenberg

was taking the position that because the HPC was removed quickly, it was evidence of layering?

A. Am I supposed to answer that?

JUDGE CHAPPELL: If you can.

THE WITNESS: Okay. I think he was -- I think he was trying to say something like that. It's a little bit confusing, because there was multiple sets of data, and one set of data showed exactly the opposite of what he said, and there were no standard curves with more than a data point. So, I'm not sure, but I think that what you're saying is probably right. I know he wasn't involved in those experiments himself.

BY MR. NOLAN:

Q. Well, let's just go down to the second sentence. I mean, I -- two sentences down, beginning "Moreover."

"Moreover, the rapid dissolution of the HPC outer layer from the ESI Lederle microcapsule (approximately one minute) further indicates that ESI Lederle's HPC does not act as a 'sustained release agent' in its formulation during the course of the sustained release of the potassium chloride."

So, do you agree that he's saying there, Dr. Langer, that the HPC in the ESI tablet functions differently than it does in the Schering tablet?

MR. LAVELLE: Same objection, Your Honor.

JUDGE CHAPPELL: Excuse me?

MR. LAVELLE: Oh, I'm sorry, same objection, Your Honor. He's asking him what Dr. Hopfenberg meant.

MR. NOLAN: No, I'm asking if he agrees that Dr. Hopfenberg made this assertion, Your Honor, and that's a starting point.

JUDGE CHAPPELL: Well, I think the question was better before what you just said, Counselor. You asked him if he agreed with what he's saying there.

MR. NOLAN: Yes.

JUDGE CHAPPELL: I'll allow that.

MR. NOLAN: Okay. Yes, Your Honor.

JUDGE CHAPPELL: So, try again.

MR. NOLAN: Could we have that question read back, please?

JUDGE CHAPPELL: So, I'm overruling the objection, but I want you to restate the question.

BY MR. NOLAN:

Q. Okay, my question -- I'll try to again -- is do you agree that Dr. Hopfenberg was asserting that the rapid dissolution of the HPC outer layer showed that ESI's tablet functioned in a different way than the Schering or the '743 patent?

A. Do I answer that?

JUDGE CHAPPELL: Yes.

THE WITNESS: I think it says what it says. I don't see that sentence talking about any comparison to Schering. I mean, I can't -- I have to agree he says the words that you read. I mean, I'm reading them, too. There's nothing in that sentence that compares the two.

BY MR. NOLAN:

Q. Do you agree that he was saying the HPC doesn't function as a sustained release agent in the ESI tablet?

A. That's what -- I -- he's saying that, yes.

Q. All right. And you're not in a position to say or are you in a position -- let me rephrase the question.

The Schering tablet used the HPC as one of the coating materials that was essential to the sustained release, correct?

A. I don't want -- I don't know enough about all the patent detail, so I don't, you know, really feel comfortable answering that. If it's on the mixing or the experiments I did, I'm happy to do it.

Q. On -- on --

A. Dr. Banker I'm sure could answer those for you, though.

Q. Thank you.

Dr. -- I mean, Dr. Langer -- and Nicole, if we could turn to Bates 699.

A. Can you help me -- is that a CX thing?

Q. The same document, next page, just turn to the next page.

A. Oh, 698 or 699? 699, I see.

Q. 699.

A. I see.

Q. There's a reference in paragraph 9 to, "These data indicate that while HPC is readily removed by water from the ESI Lederle microcapsules, HPC is not dissolved by water from the mixed polymeric coating material of the Key microcapsules." And we'll have a question, I'll direct you actually, if you could, to Bates 704, please.

A. Um-hum.

Q. And on that table, is the point of the table -- and I'm not asking you anything more than this -- is the point of the table that the HPC -- looking at sample B, and if we could highlight and blow that up a bit, that in water extraction, that HPC was removed from ESI's tablet but not from the Key sample, C and D?

A. So, your question is is that the point?

Q. Is that -- is that the -- do you agree that's

the -- that's what that table is saying?

A. This table is hard to interpret. I'd say it's further hard to interpret when you look at the data underlying it, but even on its face, it's very hard to interpret.

Q. Well, just so we can try to bring this out in English --

A. There is one data point -- there is one data point. I mean, you can't -- what can you conclude from that?

Q. Let's -- just to try to take this complex subject and describe it in English, is it fair to say what you have here is, first of all, you have a table with various samples, both ESI and Key, right?

A. Right.

Q. Just start -- we'll start there for that point there, those are both ESI and Key samples, correct?

A. Yeah, um-hum.

Q. And this is an extraction test, right?

A. Right.

Q. And the purpose of the extraction test was to see if the HPC could be extracted quickly from the ESI product, correct?

A. I believe that's -- that that was one -- that that was a goal, yes.

Q. And if it wasn't extracted quickly from the product, then it might be intermixed, correct?

A. If it wasn't -- I'm sorry, if it was -- wasn't extracted -- yes.

Q. Okay. And so the table is measuring the amount of HPC dissolved, right?

A. Yes, it says that, uh-huh.

Q. And we see, when we look at the samples, that at least sample B has HPC dissolved, there's a value of 8.22 --

A. Right, but I don't know what --

Q. -- milligrams.

A. Right. So, what --

Q. Whereas sample C and D, which are the Key products, do not.

A. But sample A doesn't either.

Q. Well, I'll take that, but I'm asking you in terms of C and D, is it correct that there was no extraction in C and D?

A. For whatever period of time we're talking about.

Q. Okay. Now --

A. But the error must be pretty big if A and B -- well, anyhow.

Q. Now, let's go back to 702.

A. 702, okay.

Q. And --

A. Yes.

Q. In 702, for what it's worth, is it correct that the only tablet -- the only sample from which there is any HPC that is being removed by water is the ESI sample B?

A. For ESI sample A I see nothing -- I would say that's true, yes.

Q. Okay. Now, if we could move on to -- well, if I may just have a moment, Your Honor?

JUDGE CHAPPELL: You may.

(Pause in the proceedings.)

BY MR. NOLAN:

Q. Well, let me just ask you without referring to a particular document.

A. Sure.

Q. Is it your understanding that ESI had Dr. Hopfenberg look at some other SEM studies?

A. My recollection was that the lawyers, Kenyon & Kenyon, for ESI asked -- I think it was Ricerca, perhaps -- again, it may have been a particular individual, to do some experiments where they basically dumped the samples into liquid nitrogen and looked at them, yes.

Q. Okay. And I guess if we would turn, Nicole, to CX 242, and Dr. Langer, if you would turn to that.

A. Yes.

Q. I believe it's just a few documents in.

A. Yes.

Q. Do you recognize this? CX 242 is a document that's dated -- or at least it's signed by Dr. Hopfenberg on May 22nd, 1987. It's referred to as the surrebuttal expert report of Dr. Harold B. Hopfenberg and Mr. William O. Butler in the matter of Key Pharmaceuticals, Inc. versus ESI Lederle.

Do you recognize this report as a rebuttal report related to SEM studies, your SEM studies?

A. Right, well, I -- I don't know enough about the exact terms. I mean, if it was rebuttal, there was no criticism of our SEM studies. They conducted some SEM studies of their own, as I mentioned before earlier, where they put stuff into liquid nitrogen, you know, which kind of cracks things.

Q. So, they conducted their own studies, right?

A. Yes.

Q. And instead of using the same procedure that you used, they chose to do something different, which is to put this into liquid nitrogen and -- correct?

A. Well, we actually did studies as well, as I

mentioned, where we did freezing experiments.

Q. You did.

A. Yes.

Q. So, you also did freezing experiments.

A. Yeah, and we couldn't see anything, and I think if you look at these, I would defy you or anybody to try to see anything in these.

Q. Is it fair to say -- now, Nicole, if you would please turn to the paragraph 3, where it says, "I conclude"?

So, Dr. Hopfenberg reached the conclusion that the SEM studies conducted -- do you agree that he reached the conclusion that the SEM studies conducted by William O. Butler confirmed his earlier opinion that the -- provided in my February 22nd, 1997 expert report, that hydroxypropylcellulose (HPC) forms a separate and distinct layer deposited upon the ethylcellulose layer in the ESI product?

A. So, is your question did he say that there or do you want me to go further than that?

Q. Do you agree that that was his position?

A. That was his position, yes.

Q. So, the Schering lawyers would know that if the case had gone to trial, that would have been something that they would have had to rebut.

A. Well, I don't think -- I mean, I actually sat there when they deposed Dr. Hopfenberg on this, and I think they -- you know, I'm not sure how to say this -- they kind of destroyed it. I mean, he had no -- he really didn't -- wasn't able to defend what he said. So, I don't think it would have been very hard for them.

I'm just telling you what happened. I mean, you can look at it. I sat there. It was -- you know, he didn't know what -- anything about it.

MR. NOLAN: I'm going to ask, Your Honor, to strike that testimony to the extent that it reflects Dr. Langer's opinion of what he heard that day, of which we cannot cross examine. He's essentially commenting on the testimony of someone in his deposition, which --

JUDGE CHAPPELL: Well, your question was, the Schering lawyers would know that if something -- that if the case had gone to trial, that would have been something that they would have had to rebut. I'm going to allow the answer. The objection is overruled.

BY MR. NOLAN:

Q. This report was something that was present in that original litigation, correct?

A. Sure.

Q. And you heard it or you heard Dr. Hopfenberg testify, correct?

A. I heard his deposition relating to that, yes.

Q. And you read this report, right?

A. Yes.

Q. So, you knew that whatever you thought of it, it was most likely going -- that ESI was doing this for a reason, right, that -- you agree that they were preparing for litigation, right?

MR. LAVELLE: Objection, two questions.

MR. NOLAN: The -- Your Honor --

JUDGE CHAPPELL: Sustained. Sustained. You asked him more than one question, Counselor.

BY MR. NOLAN:

Q. All right, you agree that ESI had an expert like you who was to appear if this matter was tried.

A. I -- I don't know how to answer that he was like me. I mean, I have published hundreds of papers and he has published none in the last ten years. I mean, it may be a legal thing, but I don't see that he has my credentials or Dr. Banker's credentials.

Q. Even if you think that you're better than him as an expert --

A. I'll let the world judge that.

Q. -- Dr. Langer, that's the point, isn't it? If

it went to trial, a judge would judge that, correct?

A. I would be happy for a judge to have judged that.

Q. And did you hear anything before that point from ESI that they were -- I mean, isn't it fair to say that they were doing this to go to trial? Let me rephrase the question, because I've asked multiple questions, but isn't the point here that ESI was actively litigating its case for trial?

A. Again, you're -- I mean, I assume they were, but I'm the wrong person to ask. There's lots of lawyers that could answer that better than me.

Q. But in terms of your experience at that time, certainly there was nothing that would indicate that they didn't think they had a side in this case, right?

MR. LAVELLE: Objection, Your Honor.

THE WITNESS: I guess I felt --

JUDGE CHAPPELL: Excuse me.

THE WITNESS: I'm sorry.

JUDGE CHAPPELL: Did I hear an objection?

MR. LAVELLE: I'm sorry, Your Honor, I did object.

JUDGE CHAPPELL: What's your basis?

MR. LAVELLE: I think there was two negatives in the question that made it hard to understand.

JUDGE CHAPPELL: Let me have the reporter read it back. If he understands it, he can answer. Overruled.

(The record was read as follows:)

"QUESTION: But in terms of your experience at that time, certainly there was nothing that would indicate that they didn't think they had a side in this case, right?"

THE WITNESS: I can't -- you'd have to ask the lawyers, not me. I mean, I felt, again, as a scientist, that their data was very weak, and I felt as a scientist, listening to another scientist, that he was very weak. That's all I could say.

BY MR. NOLAN:

Q. But that never was tested, was it, in court?

A. I don't know what was tested. There was -- I don't know more than the Markman hearing. Again, I'm the wrong person to ask those questions. I can just tell you what I saw and how I look at the data as a scientist. I have seen lots of data, and I've seen scientists answer questions. That's all I can really respond to.

Q. Just to sum up this point, the point I'm making is would you agree with me that ESI and Schering were both contesting this matter through the -- on the

particular points that you're here today to testify to?

A. Well, my sense is that we had a tremendous amount of data, hundreds of, you know, four different methods of analysis, you know, done by the top people in the United States, you know, multiple places, like Purdue and Brown and MIT. We had really, you know, outstanding data in my opinion. I'm prejudiced, but it's I think outstanding data.

They had very, very little. It wasn't even done -- it was done by some contract lab. I mean, and they couldn't defend it in a deposition. So, I don't see that as a -- you know, to me the overwhelming weight, from a science standpoint, went to Schering.

Q. You would agree with me that we spent just an hour here today, and myself, I am not a patent attorney, we looked at three -- your SEM study, and isn't it fair to say that there were only three examples in there of you looking at something where there's a cross-section at high magnification?

A. Well, that's -- but that's not the right way to look at it. Basically what we did is we did a lot of control experiments, which are very, very important to lay the groundwork for how one would interpret that, and then we looked at three different lots, three different batches that ESI prepared. All of them

showed the same thing, and they were further confirmed by a -- by literally over a hundred DSC scans, by a whole bunch of FTIRs, by a large number of dissolution studies. So, everything, all of those four separate sets of studies, you know, multiple different tests confirmed by excellent scientists showed all the same thing.

MR. NOLAN: Your Honor, I have about 30 minutes more. With your indulgence, I would like to just finish this off, about 30 to 45 minutes. If not, this would be an appropriate time for a break.

JUDGE CHAPPELL: Press on.

MR. NOLAN: Okay.

BY MR. NOLAN:

Q. Let's turn to CX 12.

A. CX 12?

Q. Right.

A. Oh, I see it, okay.

Q. And I'll identify this for the record as United States Patent 4,863,743 dated September 5th, 1989, Hsiao, et al.

MR. LAVELLE: Excuse me just a second while I check my exhibit book, Your Honor.

(Counsel conferring.)

MR. NOLAN: It also -- okay, I'll also note

that further in it it includes the prosecution history. So, it's actually more than one document. It's CX 12.

BY MR. NOLAN:

Q. I'm going to ask you -- I'm going to spend a little bit of time just talking about the patent but with the relevant purpose of putting this into some context with respect to your particular experiments.

A. Okay.

Q. Okay? Now, if we went to column 5, do you see where -- if we could blow up, Nicole, the third full paragraph down.

"The manufacturing process utilized applies a controlled and uniform coating permitting a more uniform dissolution as composed to a wax matrix and/or a coacervation formulation. Accordingly, the rapid disintegration and controlled dissolution of the tablets produced according to the present invention permit the peristaltic motion of the gut to distribute the coated crystals over a wide surface area."

JUDGE CHAPPELL: Objection?

MR. LAVELLE: I was going to wait for the question, Your Honor, but I -- we've been awfully indulgent, but it seems we're a long way outside the scope of direct, and so the objection is to being outside the scope of direct.

MR. NOLAN: Your Honor, I have a few questions related to the patent which I believe will shed some light, will be tied up in terms of the relevance or lack of relevance of these experiments. So, with your indulgence, I would just ask to ask a few of these questions.

JUDGE CHAPPELL: So, you're going to -- you're going to connect them up to what he said on direct?

MR. NOLAN: I'm going to put them in the context of where his -- what he said on -- what Dr. Langer said on direct about trying to do these experiments to find out if there was one or two layers would have some meaning or lack of meaning in light of the patent, and I promise to be as brief as I can.

MR. LAVELLE: I just want to point out to you, Your Honor, that our next witness, Dr. Banker, is going to testify about the patent and what it means in some detail, and these might be more efficiently posed to Dr. Banker.

MR. NOLAN: The --

JUDGE CHAPPELL: I am going to overrule the objection to this extent: If you want to set up a hypothetical to ask this witness based on his area of expertise, that's what I'll allow and nothing beyond that.

MR. NOLAN: Okay, the --

JUDGE CHAPPELL: Because I understand a patent guy may be coming next, but he may not be able to tell us what Dr. Langer -- what Dr. Langer can tell us, and we don't want to have to come back when this is over.

MR. LAVELLE: Thank you, Your Honor.

JUDGE CHAPPELL: Proceed.

THE WITNESS: I don't want to come back either, so thanks, not that I don't like everybody, but -- yes, go ahead.

BY MR. NOLAN:

Q. Dr. Langer, I'll ask you one question from this patent.

A. Sure.

Q. Which is that the -- it refers to a controlled and uniform coating permitting a more uniform dissolution. So, is it fair to say -- do you agree with me that the patent talks about a uniform mixture?

A. I really have to --

MR. LAVELLE: Objection, Your Honor.

JUDGE CHAPPELL: I think he's taking care of himself, Counselor, so I'll overrule it.

THE WITNESS: What I would have to say is I have -- you know, having quite a number of patents myself, I would have to read the file history and

things like that to really -- you know, and I haven't. I never did that in this case. My goal was to do experiments, and I really can't answer that question without reading the file history and things like it.

BY MR. NOLAN:

Q. So, you sitting here today, when you -- as a scientist in the area of polymer chemistry, when you hear the terms "uniform -- a controlled and uniform coating," do you agree with me or not that this -- do you agree that this refers to a mixture?

A. You'd have to read the prosecution history. You can't -- I mean, I have many, many patents myself, and so this is an area I know something about, and I guess I hate to give an answer to something that I haven't studied. I'd need to see what the underlying information is, and I haven't done that. I'm sure Dr. Banker will be able to address things like that, because I think that was his role.

Q. Do you agree with me, then, that the critical issue in terms of what -- the critical issue here, when you're looking at a patent case, is what the patent claims mean?

A. You --

MR. LAVELLE: Objection, Your Honor.

MR. NOLAN: It's -- it's -- the --

JUDGE CHAPPELL: What's the basis of the objection?

MR. LAVELLE: Calls for a legal conclusion.

MR. NOLAN: I'm not asking for a legal conclusion. What I'm asking is this witness -- Dr. Langer has been an expert in several different patent proceedings outside of this case. It's a simple point, is studies have been introduced here related to ESI product, whether it has one or two layers, and my simple question, Your Honor, is simply does he agree that it's what the patent says that matters?

JUDGE CHAPPELL: Matters to what?

MR. NOLAN: Matters in terms of infringement, not what ESI says.

JUDGE CHAPPELL: I'm not sure where that will get you, so I'll allow it. I'll overrule the objection. You can ask him that if he can answer.

THE WITNESS: I'm not a lawyer. I mean, to me, that's the kind of question -- I mean, that's the kind of question I'd want a patent lawyer to answer. You have patent lawyers you can ask that of.

BY MR. NOLAN:

Q. So, that's outside of your area of expertise?

A. I think as far as I understand the question, that's probably right.

Q. But -- so, the point --

A. Certainly in a court of law, I would feel it's outside my expertise.

Q. The point in looking at these coatings -- you looked at ESI's product, right, Dr. Langer?

A. Correct, correct.

Q. And you looked at their claim that the -- that they had a product that had multiple layers, right?

A. The way it came to me was that there were statements to the effect, I don't know whose -- whether it was Hopfenberg's or whatever, that they were separate and distinct, and I wanted to answer that from a scientific standpoint, whether that was correct or incorrect. That's all.

Q. Right. Taken in isolation, that doesn't tell -- looking at ESI's claims, even if they're wrong, doesn't necessarily mean anything, does it?

A. I can only tell you what I did as a scientist.

Q. If the -- if the ESI -- if the Schering product, if the Schering patent, calls for a uniform mixture, a uniform mixture, and your studies show -- detect some mixing, the fact that ESI failed to -- even if we assume for the purposes that your studies were correct and that ESI failed in some -- some way to produce two layers, that wouldn't necessarily show that

the '743 patent was valid -- that it was infringed, correct?

MR. LAVELLE: Objection, Your Honor.

JUDGE CHAPPELL: Basis?

MR. LAVELLE: There's two questions, and they both call for a legal conclusion.

JUDGE CHAPPELL: Let me see if it will help the attorneys, an objection without a basis is not an objection.

MR. LAVELLE: I'm sorry, Your Honor.

JUDGE CHAPPELL: When I hear an objection, I'm going to rule on it, but I need a basis.

MR. LAVELLE: Thank you, Your Honor, I'm sorry.

JUDGE CHAPPELL: Response?

THE WITNESS: Well, just to address a couple points --

JUDGE CHAPPELL: Hold on, sir.

THE WITNESS: I'm sorry, I thought you meant me. I'm sorry.

MR. NOLAN: It's a difficult subject matter, Your Honor, and what I'm trying to show is a simple point, which is -- I have not asked it in a simple way, but what I'm asking is Dr. Langer's work related to a -- what ESI said about its product, which may be true and may -- you know, or it may not be a perfect

description of its product, but what ESI says about its product is not -- has no bearing by itself on whether the '743 patent was infringed.

JUDGE CHAPPELL: Okay, but what good is his testimony in this area if he wasn't asked to form an opinion or to be involved in that subject?

MR. NOLAN: Well, the point, Your Honor, is that it's not very relevant for Dr. -- the question is, it doesn't seem very relevant for Dr. Langer to do a study about what ESI claimed if what ESI claimed and what he found has nothing to do with what the patent claims were.

JUDGE CHAPPELL: As you've just demonstrated, why do you need him to admit or deny that to make that argument? Ask the question again. I'll sustain the objection, at least the part that required a legal conclusion, and it was a compound question. So, you need to restate the question.

BY MR. NOLAN:

Q. So, Dr. Langer, you looked at the ESI product based on what the Schering lawyers asked you to look for, right?

A. I think that's an oversimplification, but, you know, basically there was a set of statements, and I wanted to understand whether those statements were

correct or incorrect and to conduct a scientific investigation to examine that.

Q. When you say there was a set of statements --

A. Right.

Q. -- those statements don't come from the patent, do they; they come from Schering lawyers who asked you to look at this?

A. I thought they came from ESI and Hopfenberg. Again, I don't know the whole history of everything. All I can say is what I did as a scientist. I thought that they were statements that ESI and Hopfenberg made. Maybe I'm wrong, but that was what I understood. I remember seeing him make statements like that.

MR. NOLAN: If I could just have a minute, and I think we're --

JUDGE CHAPPELL: You may.

BY MR. NOLAN:

Q. Dr. Banker is coming soon, right, and so I'd want to ask you some questions related to Dr. Banker.

A. Sure.

Q. Or actually related to the area of which both you and he may have some overlap.

A mixture of two polymers will not necessarily act as a plasticizer, correct?

MR. LAVELLE: Objection, Your Honor, outside

the scope of the direct.

MR. NOLAN: Your Honor, the testimony here today has related to whether two polymers are a mixture, and so in terms of appropriate cross, I think that it's relevant to gather the witness' knowledge about whether when he refers to a mixture it conforms or -- necessarily or doesn't to a particular term of art.

JUDGE CHAPPELL: Yeah, I'll overrule the objection and allow that question. I think it's fair cross.

Susanne, would you read the question back, please.

(The record was read as follows:)

"QUESTION: A mixture of two polymers will not necessarily act as a plasticizer, correct?"

THE WITNESS: I'd have to see the situation.

BY MR. NOLAN:

Q. All right, Dr. Langer --

A. Pretty consistent from five years ago.

Q. -- just from your testimony in this particular case, referring to page 191, my deposition with you:

"QUESTION: But you wouldn't think it would have to be a plasticizer, a mixture of two polymers?

"ANSWER: I'd have to see what the situation

is. I don't think -- if you are asking me does every time you have to add polymer A to polymer B, does one have to act as a plasticizer? I would have to say the answer is no. Said differently, I would stand by that answer."

A. That's right, I agree with that.

Q. You don't use the term "modifier" very often, do you?

A. I don't, no.

Q. And you don't think it's very useful as a term, do you?

A. I think it would depend on the situation and how somebody's using it. I think the context that somebody may have given it to me, which was out of context, might not be useful. I'd have to see what was said specifically.

Q. Okay, if we could look at page 192:

"QUESTION: There's a question on line 11 of page 162." I'm asking at this point, Dr. Langer, from your prior deposition.

"Are all modifiers plasticizers? Define modifiers. Have you used the term? I don't recall --" oh, actually, it's quoting from your testimony.

A. Right, five years ago.

Q. "I don't recall using that term very often."

"ANSWER: I agree with that. I don't use it often.

"QUESTION: Any particular reason?

"ANSWER: I don't think it's a very useful or precise word. But, I mean, again, it depends on the situation."

A. Yeah, and then I continue, "Somebody might have defined it more precisely." You have to see the context. So, I absolutely stand -- you have to see all the things that are written. So, I'd stand by that answer, absolutely.

Q. So, you agree with that answer?

A. I agree with what I said there, yes.

Q. And you agree that you don't think it's a very useful or precise word?

A. I think you have to read everything that's said, don't just take out what you like.

Q. Well, you used those words, correct?

A. But I also continued to use other words, and so you would have to take the whole picture if you want to be honest.

Q. You used those words in your answer, correct?

A. And I continued, that somebody might have defined it more precisely.

Q. I think it's --

A. And I continued to say you have to see it in context. That's all I'm saying. I just don't want you to take it out of context.

Q. I think it's fair to say that at least that part is a yes or no answer, whether or not -- that you testified, "I don't think it's a very useful or precise word," correct? That's one sentence there. If you take a look at it --

A. I think His Honor can read what I wrote and understands what both you and I are saying.

MR. NOLAN: No further questions, Your Honor.

JUDGE CHAPPELL: Redirect?

MR. LAVELLE: I do, Your Honor.

JUDGE CHAPPELL: Proceed.

MR. LAVELLE: Thank you.

REDIRECT EXAMINATION

BY MR. LAVELLE:

Q. Dr. Langer, would you get Exhibit CX 242.

A. Yes.

Q. You were asked some questions about Dr. Hopfenberg's SEM photographs.

A. Yes.

Q. Do you recall that?

A. Yes.

Q. Would you explain for the Court the flaws and

shortcomings you found with Dr. Hopfenberg's SEM photographs, please?

A. Yes. We -- first of all, if you take anything, I don't know if you've ever put something in liquid nitrogen, but it's incredibly low temperature, just cracks things. So, if you wanted to manufacture cracks, that's a great way to do it. It's minus 200 degrees C. So, that's -- it's just not the way you do it. It's not an accepted method of preparing samples for microscopy.

Secondly, when you look at these samples, I actually again had five people read them, it was not possible for anyone to interpret them. I mean, they're -- you could try the -- you can look at them yourself. I mean, it's -- they're not comprehensible to anyone that looked at them.

Q. Okay. And in your scientific opinion, was it possible to form any conclusions with a reasonable scientific certainty based on Dr. Hopfenberg's SEM photographs?

A. No. I want to add that it wasn't his, it was actually experiments done by the -- it was I think the lawyers at Kenyon & Kenyon asked a technician at Ricerca to do it, and then he just looked at them.

Q. And thank you again for being precise, as

you've tried to be.

I want to show you an excerpt from CX 444 that you were shown on cross examination. Somebody's got to show me how to work this.

Sir, you were asked some questions about this page 704 out of CX 444. Do you recall that?

A. Yes.

Q. And am I correct that it shows that they attempted to do two dissolution tests on the ESI product?

A. I think that's correct.

Q. Okay. And just so we're clear, the dissolution test was intended to show what, sir?

A. It was intended to show how fast the HPC would come off.

Q. And if the HPC came off quickly, what inference did that lead to with respect to mixing?

A. Then they said that there was no mixing.

Q. Okay. And if the HPC did not come off quickly, what inference did that support with respect to mixing?

A. That there would be mixing.

Q. Okay. Now, the first time that ESI did the test, no HPC came off. Is that correct?

A. When I look at the -- that's right. I don't know all these samples, but that's what I see here from

this table, yes.

Q. And the second time they did the test, some HPC came off, correct?

A. That's what I see, yes.

Q. And they were the only two samples. Is that correct?

A. That's what I see here, yes.

Q. All right. Is it possible to draw any scientific conclusion from these two samples?

A. No, and it's further complicated by the underlying standard curves that they did, which basically had one data point. Again, it's not -- nobody does one data point for standard curves. Usually you do ten or so.

Q. Do you recall how Dr. Peppas did his test?

A. Well, Dr. Peppas did a number of things. First he did standard curves with many data points. Secondly, he did a number of repeats. Third, he did it using the USP apparatus rather than, say, violent shaking. And forth, his results were very reproducible.

Q. I want to show you -- you were asked some questions about Dr. Peppas' report on cross examination. That was CX 718 in your book.

A. Yes.

Q. Do you recall that?
A. Yes.
Q. I want to show you page 7 of Dr. Peppas' report. It's ESI page 879.
A. I'm just having trouble -- well, okay, I can look at it -- yes, I'll look at it here.
Q. Are you familiar with this data from Dr. Peppas' report?
A. Yes.
Q. Now, on the left-hand column it says, "Time," and in minutes. What does that show?
A. That shows over a three-hour period -- he's doing the test over a three-hour period.
Q. So, one minute is from the beginning of the time you put the sample in water?
A. That's correct.
Q. And five minutes after you put the sample in and so forth?
A. That's correct.
Q. Okay. And as I understand it, the Sample Amount column on the far right has some significance. Is that right?
A. Right. There's 100 milligrams total. So, what you see is nothing came out after a minute. I think it says -- is that 25 -- I'm having trouble reading it on

the screen -- .195 came out, so it's about 25 percent, if I'm reading this correctly, came out after about five minutes. Even after 180 minutes, 69 percent's come out. So, this comes out quite slowly.

And in fact, using the criteria that Dr. Hopfenberg established, you would actual see 100 percent in the mixing, but if you wanted to look at it conservatively, you certainly could feel that you're getting at least more than 50 percent from the mixing.

Q. And why do you conclude from this data that there's at least 50 percent in the mixing?

A. Well, again, just to be conservative, let's take the five-minute data point. Let's say Hopfenberg were wrong or we were wrong, because we have done studies like that, too, that rather than taking one minute to come out, it would actually take five minutes to come out. Well, what that means is 70 -- since 25 percent came out, 75 percent didn't, giving ourselves some error, let's say -- does it say 28? I'm sorry.

Q. It says 28.

A. Yeah. So, basically I should say -- then I should have said 71 percent or 72 percent was still in there. So, again, even if we were -- so, that would basically say 71 or 2 percent was intermixed, but again, giving yourself some room for error, let's just

say more than half.

Q. Okay.

A. Which is what I wrote in my conclusion.

Q. And do you draw any significance from the fact that after putting the sample in water for a half an hour, only about half of the HPC came out of the ESI microcapsule?

A. Certainly it would indicate that it's significantly intermixed.

Q. Thank you, sir.

Now, I want to go back to the differential scanning calorimetry that you were asked about on cross examination.

A. Yes.

Q. And would you put up, please, Exhibit SPX 2055? Do you have 2055 in your back, Doctor?

A. 20?

Q. SPX 2055.

A. SPX -- oh, yes, okay, 2055. Yes, I see. Yes, uh-huh.

Q. Let's review just for a moment what is shown on SPX 2055.

A. Yes.

Q. The column on the left says, "Ethylcellulose-Coated Potassium Chloride Crystals," correct?

A. Yes.

Q. What was that sample? What were you testing in that sample?

A. That was the intermediate that ESI made. So, that has the ethylcellulose on it but doesn't have the HPC on it.

Q. Okay. And the column labeled "ESI's Product," what does that indicate?

A. So, that does have the HPC coating on it.

Q. And what is the significance of the fact that the heat of fusion changed between the intermediate product and the final product?

A. So, the whole point of the heat of fusion study is how much energy does it take to melt something, to go from a solid to a liquid, and if you have the crystal, there's a very characteristic melting temperature. So, the only way that melting temperature could change is something has to interrupt that crystal structure. In other words, there has to be some intermixing. And so if that melting temperature goes down, it means there has to be significant intermixing, and that makes it easier, since you've interrupted the crystal structure, it makes it easier to melt, takes less energy, and that's why the number goes down. That's the only way it can.

Q. Okay. You were asked why you didn't compare something to Schering's product. Do you recall that?

A. Yes, why did -- yes, this, for Schering's product, yes.

Q. Okay. Would Schering's -- would testing Schering's product have shed any light on whether adding HPC to the ESI product changed its melting point?

A. No. I mean, because there was no -- it was done differently. In other words, in the Schering product, they were applied as I understand it all together. So, you don't have this intermediate. The intermediate is really the right control, because you have everything but the HPC. You don't -- you never had that in the Schering product.

Q. And again, is it the absolute value of these numbers, 4.33 and 3.79, that's significant or the change or what's significant about these two charts?

A. Both, but most importantly that they're different.

Q. Thank you, sir.

Now, I want to ask you a question about the fourier-transform infrared spectroscopy that you did, and I would like to put up SPX 2054, if I can do it.

A. Yes.

Q. Do you recall you were asked some questions on cross examination about whether or not you had any controls or parameters in performing these tests?

A. Yes.

Q. First of all, would you explain what peak A and peak B in the control represent?

A. So, what was done there is you have peak A, which I believe is absolutely characteristic of hydroxypropylcellulose, and peak B, which is absolutely characteristic of ethylcellulose, let's say, and we see that throughout, whether you look at ethylcellulose by itself, hydroxypropylcellulose by itself, whether you see it with the ESI intermediate, and you see it here, which is the physical blend of these two things. So, you always see these characteristic fingerprints, A and B.

Q. Okay. And --

A. If there's no intermixing.

Q. Okay. And the red line, the yellow line in this sample, is the ESI product. Is that correct?

A. That's right.

Q. What's significant about the difference between the ESI product and the control?

A. Well, if there was no intermixing, it should look the same as the control. You should get the same

fingerprint. But in contrast, it's totally different. You see this broad peak. So, it's -- it's a totally different fingerprint. So, it tells you something had to happen to cause that fingerprint, and the only thing that can, since you have exactly the same components, is to have some type of intermixing at a molecular level, which would cause different bond stretchings and rotations.

Q. Thank you, sir.

And what is the parameter or variable here that demonstrates the mixing? Is it the height of the peaks?

A. No, it's the position and the appearance.

Q. Okay, thank you, sir.

Now, I want to ask you one question about the SEM photographs that you did, and I want to take you back to Figure 6d that Mr. Nolan asked you about.

A. Yes.

Q. All right, this is Figure 6d from your SEM photographs, correct?

A. Correct.

Q. And this is a picture of ESI's product. Is that correct?

A. That's correct.

Q. And this has the HPC added to it. Is that

correct?

A. Yes.

Q. Now, at the bottom of the photograph, there's a whitish area that I'll mark A. Can you tell us what that area is?

A. That's potassium chloride.

Q. Okay. I'm going to write KCl there, okay, do we understand that to be potassium chloride?

A. Yes.

Q. All right. Now I'm going to mark an area from the boundary of the potassium chloride to the top of the coating, and I'm going to label that B. Would you tell us what the area B is, sir?

A. Yes, that's the combination of HPC and EC.

Q. Now, you were asked about a bright region on the top of the coating that I'll label C.

A. Yes.

Q. Do you recall that?

A. Yes.

Q. And you were asked -- or you weren't asked if that was a separate layer of HPC, so I'm going to ask it. Is that area C a separate area of HPC?

A. I would say not, because what happens is when we do the controls, which are the intermediates, you see that, too. I mean, it's just a question of the

angle at which you look at something. So, we didn't see -- the point is over and over again, we didn't see a difference between the intermediates and the compressibles, the final system.

Q. And is your opinion based on one photo or two photos or how many SEM photos?

A. Well, at least six experiments compared to -- at least six experimental photos compared to at least six control photos, plus other microscopy that we did and provided ESI as well.

Q. And are the conclusions that you reached with respect to the SEM photos strengthened by or modified in any way by the other testing you did?

A. All the testing shows the same thing. Four separate sets of studies done multiple times show over and over again that there's no evidence of separate and distinct layers and that you have -- and that you are getting intermolecular mixing.

Q. And finally, would you explain to the Court why you didn't test the Schering product in the tests that you did?

A. Well, I never felt it was really relevant or the right control. In fact, the Schering product has other ingredients in it, like stearates and things like that, which could have effects on some of these tests

and may change some of the positions, and it just didn't make sense to me to take something that's got other components in it.

The beauty of the controls we did, by picking the same components that ESI kept using, we always had the same materials. So, all we did is just have different geometries, but we always had the same materials. So, that to me always seems like the best control. And again, we've done in our lab over the years thousands and thousands of experiments. That's how we do them.

Q. Okay. And having listened to the questions that Mr. Nolan asked you and having reviewed Dr. Hopfenberg's testimony from the ESI case, would you tell us what your level of scientific confidence is in the proposition that there's mixing present in the ESI product?

MR. NOLAN: Objection, Your Honor. It's not relevant what his belief as to the certainty or lack of certainty is. That would have been a question for the Court to decide.

JUDGE CHAPPELL: It's a fair question to rebut the cross examination. Overruled.

BY MR. LAVELLE:

Q. You can answer, sir.

A. Oh, it's enormously high. I mean, again, when you consider the hundreds of experiments and done four different ways, it's got to be very, very close to 100 percent.

MR. LAVELLE: No further questions. Thank you, Your Honor.

JUDGE CHAPPELL: Recross?

MR. NOLAN: I just have one question, Your Honor.

RECROSS EXAMINATION

BY MR. NOLAN:

Q. Dr. Langer, in doing your SEM studies, you never had a control that you knew for certain had a separate EC and HPC layer, correct?

A. Although we didn't, we have done thousands and thousands of SEMs in our laboratories, as has Edith. So, if there was one, we would have known it.

Q. But I think it's your testimony that you had hardly ever looked at, if ever, before this the two polymers being adjacent to each other.

A. Not by SEM. SEM, we have done things like that. I think you were referring to the FTIR.

MR. NOLAN: No further questions, Your Honor.

JUDGE CHAPPELL: Anything further?

MR. LAVELLE: Nothing further, Your Honor.

JUDGE CHAPPELL: Thank you, Dr. Langer. You're excused.

THE WITNESS: Thank you.

JUDGE CHAPPELL: It's a good time for our afternoon break. We're in recess until 3:55.

(A brief recess was taken.)

JUDGE CHAPPELL: Schering-Plough, call your next witness, please.

MR. LAVELLE: Schering calls Dean Gilbert S. Banker, Your Honor.

JUDGE CHAPPELL: Raise your right hand, please.

Whereupon--

GILBERT S. BANKER

a witness, called for examination, having been first duly sworn, was examined and testified as follows:

JUDGE CHAPPELL: Thank you, be seated.

MR. LAVELLE: Your Honor, I passed out exhibit books, and we placed one on your stand there.

JUDGE CHAPPELL: Thank you.

Sir, please state your name for the record.

THE WITNESS: Gilbert Stephen Banker.

JUDGE CHAPPELL: You may proceed.

DIRECT EXAMINATION

BY MR. LAVELLE:

Q. Dean Banker, what college of pharmacy are you

affiliated with today?

A. I'm fairly recently retired as dean of the School of Pharmacy at the University of Iowa, and even more recently retired, about a year ago, as the John Lach Distinguished Professor of Drug Delivery.

Q. What is your title at the University of Iowa today?

A. I'm now Dean Emeritus and Distinguished Professor Emeritus.

Q. Were you previously dean of the University of Iowa Pharmacy School?

A. Yes.

Q. For how long, sir?

A. I went to the University of Iowa in 1992, served as dean for about seven and a half years, and as a -- continued as a distinguished professor for another year in order to finish up some graduate students.

Q. While you were dean, did you maintain a research program?

A. I maintained an active research program.

Q. Okay. And would you describe for us how much of your time as dean you spent on research roughly?

A. At least 25 or 30 percent.

Q. Prior to Iowa, were you dean at the University of Minnesota?

A. I was.

Q. Their College of Pharmacy?

A. I was.

Q. For how long, sir?

A. University of Minnesota, College of Pharmacy in Minneapolis, and I went there in 1985 and spent seven or seven and a half years there as dean, leaving in 1992 for Iowa.

Q. And while you were dean at Minnesota, did you maintain a research program?

A. I did.

Q. Okay. And how much of your time as dean at Minnesota was spent roughly on research?

A. Again, on a percentage basis, 25 percent to a third, and you have to understand that a dean's work week is about 80 hours a week.

Q. But is it uncommon in your experience for the dean of a College of Pharmacy to maintain a research program?

A. It's very uncommon, but it's a good way for a dean to retain his or her sanity, especially when working with troublesome faculty members.

Q. Thank you, sir.

You started at Minnesota in 1985. Is that right?

A. That's correct.

Q. And where were you teaching before that, sir?

A. Before that, I taught at Purdue University.

Q. Okay. And how long were you at Purdue?

A. I went to Purdue first in 1953 as a graduate student, and four years later, in 1957, I received my Ph.D. degree and immediately went on the faculty in 1957.

Q. And you were at Purdue from 1957 to 1985 on the faculty?

A. That's correct.

Q. Okay. And for some period of that time, were you the head of the Pharmacy Department?

A. We had a group called the Industrial and Physical Pharmacy Department, which basically encompassed the area of pharmaceutics, the disciplines of industry pharmacy, physical pharmacy, biopharmacy, and I did -- I was the first chair of that department, the first department head, and I served in that role for 18 years.

Q. Thank you, sir.

While you were at Purdue, did you actually have experience in manufacturing drug products?

A. Yes, throughout my entire period of time on the faculty, I was very involved. Most of the time I was

in charge of an industrial pharmacy laboratory where we actually manufactured products for human consumption, and these products were used by the university hospital and the university out-patient pharmacy. We manufactured probably a hundred different products. We didn't manufacture injectables, but about everything else.

Q. Very good.

Sir, have you authored articles of original research in the area of pharmaceutics?

A. I have.

Q. Approximately how many?

A. Counting the articles, the patents, the books and the book chapters, it's about 150.

Q. Very good.

Do you serve on advisory boards for research journals relating to pharmaceutics?

A. I do. I serve on three or four.

Q. Okay. Do you serve as a referee for research journals in pharmaceutics?

A. I did.

Q. Any particularly notable ones?

A. Yes, I'm flipping to page 8 of my CV, because I don't want to miscredit who I work with. Pharmacy International is a journal produced by the -- or

published by the Federation Internationale Pharmaceutique. It's the worldwide pharmacy federation, and I serve on that journal.

And then another very major international journal is the International Journal of Pharmaceutics, and I'm on the editorial board of that journal. And then we heard from Dr. Langer this morning about the American Association of Pharmaceutical Scientists, which is the lead U.S. organization, although it's now very international, and they have a periodical, Pharmaceutical Development and Technology, and I'm on that board. And I'm on another advisory board for a journal called Pharmaceutical Technology.

Q. Thank you, sir.

Now, you referred to your CV. Could I direct you to Schering Exhibit SPX 720, please, sir?

A. I have it.

Q. Would you identify that for us, please, Dean Banker?

A. That is my curriculum vitae.

Q. Okay. And is it accurate and reasonably complete, sir?

A. I think it's quite current.

Q. Thank you, sir.

How many years of experience do you have in

research and education in pharmaceutics and pharmaceutical coatings?

A. My experience in pharmaceutical coating basically started at the very beginning of my academic career, back in 1957. So, it's close to 45 years.

Q. Thank you, sir.

What are your major areas of research interest?

A. My primary areas of research interest are coatings, polymer coatings, new polymers, new polymer excipients, nondrug components, sustained release product design.

Q. Have you authored any works in the area of pharmaceutical coatings or pharmaceutics?

A. I've authored numerous works in the area of pharmaceutical coatings, one that goes back about 30 years, "Film Coating Theory and Practice," was a review article that I still get requests for, but if you go through my CV, you'll find half or more of my articles probably relate to coatings, polymers.

Q. And are you one of the co-editors of a leading treatise on pharmaceutics?

A. I am.

Q. And what's the name of that work, sir?

A. Modern Pharmaceutics.

MR. LAVELLE: Your Honor, may I approach the

witness?

JUDGE CHAPPELL: Yes, you may.

MR. LAVELLE: Thank you, Your Honor.

BY MR. LAVELLE:

Q. Dean Banker, would you identify Schering Exhibit SPX 2158 for us, please?

A. I will. It's the current edition of Modern Pharmaceutics, the third edition. The fourth edition will be out this summer, and Modern Pharmaceutics is basically a book that describes drug product quality, how drug products are designed, how they're evaluated. There are selected chapters on topics like sustained and controlled release. There are chapters on tablets, there are chapters on -- sections on coatings, and it's a book that's used all over the world. The sales outside the U.S. are as great as those in the U.S.

Q. And who uses -- who consults the work Modern Pharmaceutics?

A. It's a widely used textbook in colleges of pharmacy. It's to be found on the bookshelves of a great many pharmaceutics faculty members, as I've traveled around the world I'm pleased to see, and it's used widely in pharmaceutical research laboratories.

Q. Thank you, sir.

Do you hold any patents on pharmaceutical

patents?

A. I believe I have 13 patents, and of the 13, the majority involve coatings.

Q. Okay. You're aware that the '743 patent in this case relates to ethylcellulose coatings, aren't you?

A. I am.

Q. Do you have any particular experience in ethylcellulose coatings?

A. Yes, I have a lot of experience in ethylcellulose coatings, and I might mention why. Ethylcellulose is a derivative of cellulose, and cellulose makes up over a third of the plant kingdom. Cellulose, of course, is completely safe, nonirritating, nontoxic, and so derivatives of cellulose have the greatest acceptance in the Federal Food and Drug Administration for drugs and foods, and ethylcellulose is the most commonly used of all water-insoluble polymers in pharmaceuticals.

Q. Do you hold any patents on ethylcellulose coatings?

A. I do. There's a significant patent that changed the way ethylcellulose could be employed in the pharmaceutical industry.

Q. Are you aware of a product called Aquacoat?

A. Yes, that's the trade name of the product that John Vanderhoff at Lehigh University and I developed and invented, and I might -- I might comment that the reason that remade how people used it was before Aquacoat, any time you wanted to coat with ethylcellulose, you had to use an organic solvent, because it's not water-soluble. So, you had to dissolve it in alcohol or alcohol and a chlorinated solvent, and the EPA doesn't like chlorinated solvents, and they can be carcinogenic.

So, John and I came up with a way to make tiny little beads of ethylcellulose that could be dispersed in water and form nice films and be used for case masking and controlled release and the like, and FMC, a corporation in Philadelphia, now manufactures it worldwide.

Q. Very good, sir.

Do you consult with pharmaceutical companies in the fields of drug coating and drug design?

A. I have.

Q. Okay. Do you consult with generic companies?

A. I have.

Q. Where did you get your Ph.D., sir?

A. I got my Ph.D. at Purdue.

Q. Okay. Did you get your Master's at Purdue?

A. I did.

Q. Are you a member of the American Chemical Society?

A. I am.

Q. Are you a member of the American Pharmaceutical Association?

A. I am.

Q. Are you a member of the Academy of Pharmaceutical Sciences?

A. I am.

Q. Are you a fellow in that organization?

A. I am a fellow in that organization.

Q. What does it mean to be a fellow in the American Pharmaceutical -- the Academy of Pharmaceutical Sciences?

A. A number of scientific organizations grant fellow status to perhaps 5 percent of their members who have made the greatest contributions to science in their field.

Q. Are you a member of the American Association for the Advancement of Science?

A. I am.

Q. Are you a fellow in that organization?

A. I am.

Q. Are you a member of the Academy of

Pharmaceutical Research and Science?

A. I am.

Q. Are you a fellow in that organization?

A. I am.

MR. LAVELLE: Your Honor, I would like to offer Dean Banker as an expert in pharmaceutical coatings and in the design and evaluation of pharmaceutical products and dosages.

MR. NOLAN: No objection, Your Honor.

MR. CURRAN: No objection, Your Honor.

JUDGE CHAPPELL: Hearing no objection, your offer is accepted.

MR. LAVELLE: Thank you, Your Honor.

BY MR. LAVELLE:

Q. Dean Banker, did you act as an expert for Schering in the ESI case?

A. I did.

Q. And generally, will you tell us what you did in that case?

A. I reviewed the ANDA, the abbreviated new drug application, that ESI had submitted to the FDA. I reviewed other documents, including certification documents that had been submitted to Schering and Key. Of course, I later reviewed depositions and other items.

Q. Did you prepare expert reports in the ESI case?
A. I did. I did.
Q. And did you testify at the Markman hearing?
A. I did.
Q. Thank you, sir.
Sir, would you turn to Exhibit SPX 194 in your book?
A. I have it.
Q. And do you recognize Exhibit 194 as the Schering patent at issue in the ESI case?
A. I do.
Q. And was it also the patent at issue in the Upsher case as well?
A. It was.
Q. And you understand that today we're going to talk exclusively about the ESI case?
A. I do.
Q. Will you tell the Court generally what the invention is in the '743 patent?
A. The invention of the '743 patent was a breakthrough invention, and it involved a method of making potassium chloride tablet in which the tablet was comprised of little small potassium chloride crystals that were coated with ethylcellulose and hydroxypropylcellulose, a polyethylene glycol, to put a

flexible coating around the potassium chloride, allowing the potassium chloride crystals to then be compressed in the tablets, and these tablets in turn, when given to a patient, very quickly, within just a matter of a few minutes, totally disintegrated, released the coated potassium chloride crystals intact, without the coating being ruptured or cracked or deformed so as to allow premature release of the potassium chloride.

Q. Thank you, sir.

Now, the active ingredient in the drug was what?

A. Potassium chloride.

Q. Okay. And did you refer to it as a sustained release product?

A. It's a controlled, sustained release product. I may have left that out, but it was a sustained release product.

Q. What -- thank you.

What does that mean, to be a controlled or sustained release product?

A. That's -- the sustained release element is an important feature of this product. Potassium chloride is what's termed a strong electrolyte, and sodium chloride would be another strong electrolyte, salt,

something we're familiar with, and potassium chloride suffers from the same difficulty that sodium chloride does when you're trying to give high doses. If you have a child who consumes a poison and as a home precaution you want to administer something that's going to cause that child to vomit, you mix up a good concentrated salt solution and have him drink it, and they will vomit promptly.

So, the same is the problem with potassium chloride. If you have it released in the stomach rapidly, it will be an emetic, and this is not what the elderly people are looking for that are taking it for their hypokalemia.

The other thing you want to do is not have the potassium chloride crystals, if you can possibly avoid it, contact the gastric mucosa or the intestinal mucosa, because being a strong electrolyte, they're very irritating, potassium chloride is, and if you had a tablet of potassium chloride that was hung up in a loop of the intestine, it could produce an ulcer and, in fact, did produce ulceration in patients. So, that was something you wanted to avoid, and for years people tried to design sustained release products that would gradually release potassium chloride and reduce these deleterious effects to the patient, but these -- these

attempts were fraught with difficulty and only really resolved through the Hsiao patent.

Q. You used a word there, you said that potassium chloride can be an emetic?

A. Emetic, E M E T I C.

Q. What does that mean?

A. Emesis is vomiting. An emetic is an agent that will induce vomiting.

Q. Sorry I asked.

Generally speaking, why do patients need to take potassium chloride?

A. Patients who are on diuretics, and many elderly people who have heart disease, congestive heart failure or edema associated with decreased cardiac function tend to accumulate fluids in their body, and they have swollen legs, swollen ankles, and so they give these diuretics to get the water out of the body, which is usually accomplished by urinary excretion, but the difficulty is that potassium, an essential element to life, is eliminated in large quantities with these diuretics, and the people who take the diuretics get what's called hypokalemia, which is low potassium in their body, which can be a very serious event, because it can lead to all kinds of cardiac difficulties, very serious side effects. So, you have to put the

potassium back in.

Q. And how large are the doses of potassium chloride that patients take typically?

A. They're enormous. The typical dose in potassium supplementation therapy, pardon me, is 20 to 40 milliequivalents. Twenty milliequivalents is 1.5 grams. I'll put that in perspective. An aspirin tablet is a little over a third of a gram. So, when you're taking 1.5 grams of medicine, you're taking like five aspirin tablets, and the usual dose, as I said, is 20 to 40, so you might be taking the equivalent of ten aspirin tablets, and some people have to take 60 to 80 milliequivalents a day for their supplementation. So, the doses are very large.

Q. Do the large doses that are required post challenges for the people who design this drug product, potassium chloride?

A. They do.

Q. Would you explain that?

A. But let me, if I may, say that the large doses, first of all, pose horrendous challenges to the elderly people who are taking the medication. You can't take your one-day supply of potassium supplementation at a time, you'd flood your system, you would get too much potassium release, you could get emesis, you could get

visual disturbances, all kinds of side effects of overdosing of potassium on a dump, so you need to space it out, and until Charlie Hsiao came along with his invention, the largest dose that could be given was 10 milliequivalents in any solid dosage form.

So, if you're on an 80 milliequivalent dose, you would need to take eight tablets a day, can't take them all at once, should take them eight different times, and to get an elderly patient to remember to take medication eight times through the day is pretty challenging. I know, because I'm getting in that population.

So, that was the -- that was a big challenge for the patient along with the toxicity and not being a very safe presentation, but the challenges to the formulator were how can you get the maximum amount of potassium chloride in a single tablet and reduce the number of times the person has to take the tablet, and how can you have it be gradually released, in solution, slowly, so you don't produce a concentrated solution of potassium chloride anywhere in the gut to produce a lesion, and how can you manage all this with a drug that is very soluble?

Potassium chloride has solubility similar to sodium chloride. You can dissolve a gram in only a

couple milliliters. The other -- some of the other problems are potassium chloride, like salt, tends to be a cubic crystal with sharp edges. If anybody had told me you could successfully coat it and compress it into a tablet and make a gram and a half tablet, I would have told them it was impossible, don't even bother trying, because I did once. So, it's -- it's got formidable challenges, and designing the product from a rational basis, to provide an ideal presentation to the body, which would be to have very small particles that are coated, to have the potassium chloride crystals never see the gut, all the gut ever sees is the drug in solution, and to have thousands of these particles that are compressed into a tablet without destroying the coating or rupturing the coating or allowing the drug to dump, formidable challenges.

Q. Let's talk about the '743 patent for a moment, okay? How did the inventors address these drug delivery challenges?

A. Well, they addressed them by taking potassium chloride crystals that are 30 to 50 mesh, and if I can --

Q. Just what does that mean, 30 to 50?

A. If I can explain what mesh size means, mesh relates to a screen, and in pharmacy and chemistry, it

relates to the number of wires per linear inch in the screen, and if you think about the screen that you have on your porch to keep the mosquitoes out, that might be down around a 40 or 50 mesh, there are 50 wires and then there are openings between these wires, so there are 50 wires in each direction per linear inch for a 50-mesh screen, 30 wires for a 30-mesh screen. The lower the screen number, the larger the particle therefor.

To let you know what the particle size is, we will get into what a micron is maybe, but it produces particles of 300 to 500 microns. I can explain a micron. A meter is a little longer than a yard. There are 39 inches in a meter, and in one meter, there are a million microns. So, you can divide a million by 39, and you'll know how many microns are in an inch, a whole bunch of them.

In a -- in a 50-mesh screen or -- yeah, in a 50-mesh screen, you'd have about a 50-micron particle size.

Q. Are particles roughly the size of salt crystals?

A. Yeah, roughly the size of a salt crystal out of a salt shaker, they would be in that range.

Q. Okay, taking crystals of sodium chloride or

potassium chloride about that size, how did Key address the drug delivery problem in the '743 patent?

A. The '743 patent really focuses on a polymer coating, and they found a way to modify ethylcellulose, to plasticize ethylcellulose, and make it so durable and so flexible that you could put this coating around the potassium chloride crystals and then take the coated crystals and put them on a tablet machine.

The way you make tablets are there are two punches that come together in a dye, and the tips of the punches have the shape of the tablet, the round contour of the tablet, and the dye is just a trifle larger than the two punches, and as the two punches come together, they compress the material.

The forces that are used are thousands of pounds. It would be like putting a Volkswagen on top of that punch to compress the material. The pressures that are used are more than that, because pressure is force per unit area, and these tablets have less than a square inch. So, you're looking at pressures of maybe 4000 or 5000 pounds per square inch.

And to do that, compress that tablet, make a cohesive compact, which is what we like a tablet to do, cohesive, hold together, not break up in your purse or your pocket or your bottle in your medicine cabinet, is

a challenge. It requires these high pressures, but to be able to do that and not rupture the coating, it would be like taking a bunch of M&M candies and trying to comprise them together to make a solid compact and not rupture the coating on the M&M. It's the same kind of thing.

Q. Very good.

Let me show you Schering Exhibit 2037, SPX 2037.

Your Honor, may I approach the witness briefly?

JUDGE CHAPPELL: Yes, you may.

BY MR. LAVELLE:

Q. Dean Banker, could you identify Exhibit 2037, please?

A. Yes, this is Schering's K-Dur 20, which is their trade name for their potassium chloride extended release tablets -- extended release is another way of saying sustained release -- and it's for 20 milliequivalent dose or 1500 milligrams, a gram and a half.

Q. And is that product made in accordance with the teachings of the '743 patent?

A. It's made I believe completely within the teachings of the '743 patent, even to the formulation listed in the patent.

Q. Very good.

Would you take one out and show us the size of that pill, please, tablet?

A. It's a large tablet, (indicating.)

Q. Thank you, sir.

Is there a score line or a center line on that tablet?

A. There is a score line on the tablet.

Q. What's the purpose of the score line?

A. It's twofold. You can readily break the tablet in half. With most sustained release products, if you try to break the tablet in half, you'll destroy its sustained release characteristics. Most tablets have a coating around the tablet as a whole, and as soon as you rupture or distort or break that coating, you're going to get dumping.

In this case, because -- and you'll notice, Your Honor, where I broke the tablet, there are very few -- very few -- there are just a few crystals on top of the book and on my finger, and if you were to analyze these under a microscope, I bet you'd find that they're still coated. They're still intact. That's how durable this coating is.

But by breaking it in half, an elderly person can probably swallow this (indicating), while they

might not be able to swallow what we in pharmacy call the horse pill, and so that's one advantage. They can break it in half and readily swallow it.

The other advantage is you might have a doctor write for not 20 milliequivalents but 30, so you can just split one tablet and take half of one and a full one of the other and you've got your 30.

Q. Thank you, sir.

Was there anything novel or original about Schering's K-Dur 20 product?

A. As I've indicated, it was -- there aren't many inventions that come along that are really kind of earth-shaking in what they do as far as advancing therapy with a particular drug or in a particular field, but this was one such case. Until -- until this product came along, until this tablet became available, the largest dose a person could take was in a capsule, and it was only 10 milliequivalents.

The other -- the other thing that the other formulations did not address was how to meter very small, coated particles out of the stomach, into the intestinal tract, and have the gut only see these little tiny 40-mesh coated particles, and the only way they see the drug is when the drug diffuses out of those coated particles in solution, and the particles

get distributed widely, because in your stomach they get mixed up with food, they gradually meter out. Your stomach sees them only as a coated particle, and the stomach only sees the drug in solution.

So, if you're thinking about the ideal way to deliver potassium chloride, this would be it. The only question was how on earth do you design the system? Well, Charlie Hsiao figured out a way to do it, and I didn't think it would have been possible.

Q. Okay. Would you turn to Exhibit SPX 721, please, in your book.

A. I have it.

Q. And is that an article from the -- from the textbook Modern Pharmaceutics that you have in front of you?

A. It is.

Q. All modesty aside, is Modern Pharmaceutics generally accepted as reliable in the area of pharmaceutics?

A. It is, and part of the reason for that is Dr. Rhodes and I are able to get very renowned people in the pharmaceutical field to author the chapters, people who are really expert.

Q. And let's look for a moment at the chapter on tablet dosage forms that's in Exhibit 721. Do you have

that?

A. I have it.

Q. Who wrote that chapter?

A. That chapter was written by Ed Rudnic and another young lady who had worked with Dr. Rhodes at Rhode Island, Mary Kathryn Kottke. Those were two of Dr. Rhodes' former graduate students. And you'll see on the cover that Dr. Rhodes and I co-edited this.

Q. Very good.

The authors in Exhibit 721 called the K-Dur product "a simple but elegant formulation which is a masterpiece of solid dosage form strategy to achieve clinical goals." Is that correct?

A. That's correct, and if you go down on page 334, if you go down on 334, one, two, three, four -- five paragraphs, a little lower than the middle of the page, that's the last sentence in the paragraph, and it talks about tablets who have combined -- that combine sustained release characteristics with a rapidly disintegrating tablet, and they specifically mention the K-Dur product, and they mention that the crystals are coated with ethylcellulose, a water-insoluble partner, and then in a rapidly disintegrating matrix, and they say the purpose is to minimize GI ulceration commonly seen with KCl therapy, and then they make the

statement, "This simple but elegant formulation is a masterpiece of solid dosage form strategy to achieve clinical goals," and the clinical goal was to reduce irritation and toxicity.

Q. Do you agree with the assessment?

MR. NOLAN: Your Honor, I just would like to note an objection that the document is not a complete document, and it's possible that we were just presented with a complete document this morning, but I'm not sure, but I would like to see -- to receive from Schering's counsel a complete document, not one that is cut off.

MR. LAVELLE: Your Honor, it is -- the exhibit that we've put into 721 is an excerpt from SPX 2158, the book, and we will, of course, give them a complete copy of the article.

MR. NOLAN: Thank you, Your Honor.

JUDGE CHAPPELL: So, with that, do you withdraw your objection?

MR. NOLAN: Yes, as long as we get a complete copy of this article 10, which we don't have that even.

JUDGE CHAPPELL: So, as I understand it, Mr. Lavelle, you're giving opposing counsel a book --

MR. LAVELLE: We will get them a book, Your Honor.

JUDGE CHAPPELL: -- plus the exhibit you're talking about?

MR. LAVELLE: Absolutely, Your Honor.

JUDGE CHAPPELL: Okay, thank you.

MR. NOLAN: Thank you, Your Honor.

BY MR. LAVELLE:

Q. Do you have a cup of water there, sir?

A. I have some water. I don't have a cup.

MR. LAVELLE: If I may, Your Honor?

JUDGE CHAPPELL: Of course, you may.

MR. LAVELLE: Thank you.

THE WITNESS: I might add, while you didn't ask me, I agree with the two authors of that chapter, that it was a -- what they said, I completely agree with. It was such a breakthrough.

BY MR. LAVELLE:

Q. Thank you, sir.

I wonder --

JUDGE CHAPPELL: Dr. Banker, I need to request that you not respond when a question is not pending.

THE WITNESS: I'm sorry, I'll do that.

BY MR. LAVELLE:

Q. I'm wondering if you would take the pill and the water and explain to us what happens when the patient swallows the pill.

A. When a patient swallows the pill, it immediately goes into the stomach, down the esophagus and into the stomach. The stomach typically has 200-300 mils of gastric fluid, and after a meal it may have considerably more, and as I drop the tablet in the glass of water here -- this is not gastric fluid, gastric fluid is acidic -- but potassium chloride is soluble in water or gastric fluid to virtually the same extent, even if the media is acid, and it's already starting to fluff up and expand, and the tablet contains something called a disintegrant that helps blow the tablet apart and release the coated particles.

The coated particles are already forming on the bottom of the glass, and within about two minutes, the tablet will have been completely -- will completely disintegrate, even though that's cold water, not body temperature water.

Q. Once the tablet disintegrates, how does the potassium chloride do its job?

A. The potassium chloride comes out of the coating by a permeability or diffusion process. Water goes in through the coating, and the water that goes into the coating dissolves the potassium chloride, then the potassium chloride in solution diffuses out -- diffuses out through the pores of the coating.

Q. Are there difficulties associated with coating crystals of potassium chloride?

A. Yes, I mentioned some perhaps. One --

Q. Would you explain that to us a little bit, please?

A. All right. One is potassium chloride, like sodium chloride, tends to be a cubic crystal, and cubes have sharp corners. The easiest thing to coat is something spherical that doesn't have any sharp corners, because where you have sharp corners, your coating's going to be the thinnest and most prone to rupture.

The other difficulty is this drug is so very water-soluble that if you have any defects in your coating, the drug will dump. It will come out within a minute or minutes. So, that's a challenge. And those are the -- I think the two primary challenges.

There is one other. You're coating an enormous number of small particles. I judge there are probably at least a thousand potassium chloride particles here, and each and every one has to be coated and has to be uniformly coated. There are a couple of ways -- they call this coating process microencapsulation, and there are a couple of ways you can do it, but it's a challenge to accomplish, but it's a much bigger

challenge to accomplish so that you can compress them into a tablet.

Q. Prior to Schering's K-Dur 20, had others tried to make a tablet of microencapsulated potassium chloride?

A. Yes, I'm aware of reading some documents that a scientist by the name of Larry Miller, who I know casually, worked for ten years to try to produce a potassium chloride tablet of this type, and then there was a fellow in New Zealand, I believe, who worked on his Ph.D. thesis, and his challenge was to coacervate, microencapsulate, potassium chloride, and he worked for I don't know how many years, I don't know how long his Major Professor kept him around when he couldn't successfully do the job, but he wasn't able to coat potassium chloride crystals.

And at Purdue, we often had special projects in our graduate course, and I've tried to coat potassium chloride crystals and compress them into a tablet, and failed.

Q. You mentioned Mr. Larry Miller. Do you recall what company he was with when he made his efforts to create this tablet?

A. He was I believe with A. H. Robbins.

Q. Let me just show you briefly Exhibit --

Schering Exhibit SPX 723.

A. I have it.

Q. And do you recognize that, sir?

A. Yes, this is the Ph.D. thesis I was referring to from Dunedin, New Zealand.

Q. It's the thesis of a Mr. Dennis Robinson?

A. It is.

Q. And it was submitted in pursuit of his Ph.D. at a college in New Zealand?

A. It was.

Q. In 1985?

A. Yeah.

Q. And what is the significance of this document to the testimony you just gave?

A. Well, he worked extensively to microencapsulate potassium chloride, and he had a great deal of difficulty. He reports in his summary and conclusion that ethylcellulose coacervate droplets do not readily adhere and coalesce around potassium chloride crystals because of high energy surface and the hydrophilic nature on dissolution of the encapsulated drug. The osmotic pressure generated, that would be by the potassium chloride, readily ruptures the thin walls, that would be of the coating, and these factors together with the existence of pores in intact walls

cause a rapid in vitro release, even when common core-to-wall ratios -- which is one to one, so that's an enormous ratio. That would have a thickness as great as the particle itself. You would have an enormous amount of ethylcellulose.

And at one other place in here he talks about his T50 percent releases, which are the time it takes for 50 percent of the drug to come out, and those values were in minutes, just a few minutes.

Q. In plain English, did it work or did it not work?

A. He wasn't able to make it work.

Q. Okay. Let's go to Schering 194, the patent again.

A. All right.

Q. You gave testimony or you prepared expert reports in the ESI case about whether or not this patent was infringed by ESI's product, didn't you?

A. I did.

Q. Okay. And do you understand generally that patents have what are called claims?

A. I do.

Q. And that those claims, do you understand generally, relate to the exclusive right of the invention?

A. I do.

Q. And in the Schering patent, those claims are the numbered paragraphs 1 to 12 that start in column 8, right?

A. I understand that.

Q. And in the ESI case, did you compare some of the claims of this patent to the ESI product?

A. I did. I tried to claim -- compare them side by side.

Q. Okay. I'd like to show you SPX 2038, which is a copy of claim 1 of the patent, and it's in your book as well, sir.

A. I have it.

MR. LAVELLE: Your Honor, I just might mention for the record that claim 1 as printed in the patent had a small typographical error, which was corrected by a certificate of correction, which was attached to the patent. In reproducing 2038, we corrected the typographical error in claim 1.

JUDGE CHAPPELL: Okay, thank you.

BY MR. LAVELLE:

Q. Sir, do you recognize claim 1?

A. I do.

Q. I would appreciate it, sir, if you would walk through claim 1 and just explain for us what each of

the elements of that claim are.

A. Claim 1 begins by stating what the dosage unit is or the dosage form, and the dosage unit is a tablet, and the tablet is for oral administration, for oral administration of potassium chloride. So, that's the preamble.

And then to accomplish that, that tablet comprises a plurality, a great many, coated potassium chloride crystals, with the amount of potassium chloride in the dosage unit being in the range of 68 to about 86.5 percent by weight based on the total weight of the dosage unit. So, most of the dosage unit is potassium chloride.

Going on, a coating material, a coating material for the individual potassium chloride crystals, the coating material comprising ethylcellulose in the amount in the range of about 9 to about 15 percent by weight based on the total weight of the coated crystals, and at least one member selected from hydroxypropylcellulose or polyethylene glycol in an amount in the range of about 0.5 to about 3 percent by weight based on the total weight of the coated crystals, said ethylcellulose having a viscosity greater than 40 cp, and cp stands for centipoise, which is a viscosity unit.

Q. Okay. What is the principal coating material that's involved in claim 1?

A. Ethylcellulose.

Q. Okay, fine. And what are the -- can I call the hydroxypropylcellulose HPC this afternoon?

A. You can.

Q. And can I call the polyethylene glycol PEG?

A. You can.

Q. And we will be communicating?

A. Yes, we will.

Q. What are the HPC or PEG doing in this patent claim?

A. They're rendering the ethylcellulose flexible and durable and taking away from ethylcellulose its native brittleness so as to allow compression of this coating around the potassium chloride crystals into a tablet without rupturing, having the coating be ruptured. So, they're modifying the ethylcellulose or plasticizing the ethylcellulose, they're making it very flexible, durable, and they're strengthening the film.

Q. What's a plasticizer, sir?

A. A plasticizer is a material added to a polymer to enhance its elasticity, give it more stretch, to make it more flexible, to make it stronger, to make it more durable and to reduce brittleness.

Q. Now, that last element says that the ethylcellulose has a viscosity of greater than 40 cp.

A. Yes.

Q. Would you explain what viscosity is, sir?

A. Very briefly, viscosity is resistance to flow. The water here has a low viscosity. It very readily flows. If I had a jar of molasses, I could turn it upside down and it might not flow. It would take time to flow, and that would have a high viscosity. It would have a high resistance to -- to flow. So, viscosity is simply a measurement of resistance to flow.

Q. Okay. And do manufacturers of ethylcellulose sell it in different viscosities?

A. They do.

Q. Okay. And would you explain what the relevance is of the viscosity to the ability to coat the potassium chloride crystals?

A. Yes. Viscosity of a polymer is a way of characterizing the polymer's molecular weight. Polymers are comprised of repeating units of a common chemical structure, and these repeating units repeat time after time after time and produce a long chain, which is what a polymer is. It's an extended configuration. And we're talking about ethylcellulose

here.

Ethylcellulose is a derivative of cellulose, a natural polymer, and natural cellulose will have, oh, 1000 or 1500 repeat units. The repeat units are called anhydrogalactose (phonetic), which is neither here nor there, but what you can do is you can take your polymer and dissolve it in a standard solvent at a fixed concentration, and you can characterize your polymers by molecular weight groupings according to viscosity, and so you can call it 40 cp or 40 cps grade, and this will correspond to -- for ethylcellulose, this corresponds to about 60,000, a molecular weight of 60,000.

Q. Okay. And what does the viscosity of the ethylcellulose have to do with your ability to coat the crystals and make tablets?

A. The longer chains have more intertwining. When you form a film, the polymer chains interconnect and intertwine, and so the longer chains are harder to pull apart, to pull a film apart, and so the higher molecular weight materials generally give a stronger film, maybe not a more flexible film but a stronger film. So, you would like to have a higher viscosity, higher molecular weight grade to have a strong film, but you have a competing objective.

When you dissolve a higher molecular weight polymer in a solvent, it's going to take up a lot more solvent, because it's more viscous, and to be able to spray it through a spray gun, as you would if you're coating the side of a house, it needs to be reasonably fluid. So, if you've got a low viscosity ethylcellulose, you might be able to spray a 20 percent solution. As a matter of fact, I have. If you're trying to spray a 100 cps grade, instead of making a 20 percent solution, you can only make a 2 percent solution. So, you have to use an enormous amount of solvent to put the same amount of polymer on a surface.

So, there are competing objectives. You'd like the higher molecular weight, but that's going to cost you. You're going to have to use a lot more solvent to apply it.

Q. Now, you mentioned spraying the ethylcellulose. Perhaps we should explain how you coat the ethylcellulose onto a -- onto a crystal in the Schering process.

A. In the Schering process, they have something called a Wurster tower. Dean Wurster was my predecessor at Iowa and developed this technology when he was at Wisconsin, and it's basically a column, and it has air blowing in from the bottom, and the air

lifts the particles, whether they be crystals or granules or tablets. This process is called fluidization.

I might, Your Honor, equate it to Power Ball. You've probably seen ping-pong balls on television for Power Ball, where the ping-pong balls are suspended in air, and they open a little thing at the top and a ping-pong ball -- what they are doing is fluidizing the ping-pong balls.

Well, in the Wurster coating, they are doing the same thing. They are fluidizing the particles, and then they have a spray head up in the top of the column, or it might be in the bottom, and as the materials are tumbling, they add this spray, which coats the particles.

Q. Very good, thank you, sir.

Going back to the words of claim 1 that are shown in Exhibit 2038, for example, does -- do the words of claim 1 contain any requirement as to how the tablet must be made?

A. No.

Q. And does claim 1 talk about or state to you, as one skilled in the art, whether or not the ethylcellulose and the HPC have to be mixed?

A. The claims say nothing about that.

Q. Okay. How much time did you spend preparing for your testimony in the ESI case?

A. Hundreds of hours.

Q. Okay. Do you recall that that case was pending in a Federal Court in Philadelphia?

A. I do. I was waiting to testify when they woke me up the next day and said I didn't have to.

Q. And why didn't you have to testify?

A. They settled it in the wee hours of the morning.

Q. And do you recall the case settled in January of 1988 -- '98, about?

A. Yeah.

Q. And do you recall the case started in about February of 1996?

A. That's about right.

Q. Okay. And do you recall that Key was suing ESI for infringement of this '743 patent?

A. I do remember that.

Q. In the course of that case, did you become familiar with the potassium chloride tablet that ESI had formulated?

A. I did.

Q. Okay. How did you become familiar with -- what did you do to learn about the product?

A. A number of things. ESI had prepared an abbreviated new drug application for submission to the FDA. That was made available to me. They also had prepared a disclosure to Schering, I think they call it a certification, letting Schering know that they were going to apply for this abbreviated new drug application, letting Schering know what their technology was, and they were required to do this because Schering held the parent patent.

Q. Do you recall what ESI called its product?

A. Micro-K 20.

Q. Okay. And what was the dosage form of the Micro-K 20?

A. It was a tablet.

Q. Okay. How -- how large was the dose?

A. The dose was 20 milliequivalents.

Q. And is that the same as the Schering dose?

A. It is.

Q. The active ingredient in the Micro-K 20 was what, sir?

A. Potassium chloride.

Q. How did the dosage form or the amount of the dosage of ESI's product differ from Schering's?

A. They didn't differ. They were the same dose.

Q. Okay. What was the coating material of the ESI

tablet?

A. The coating material was ethylcellulose and HPC.

Q. Are they the same materials that Schering used?

A. They are.

Q. What was the viscosity of the ethylcellulose in the ESI product?

A. It was greater than 40. It was actually 100.

Q. And do you know what Schering uses?

A. They use 45.

Q. Thank you, sir.

I want to show you SPX 2041, please. Would you go to that in your book?

A. I have it.

Q. Can you tell us generally first what this is?

A. It's a comparison of claim 1 of the '743 patent with the ESI product.

Q. And what's shown on the left-hand side of Exhibit 2041?

A. The elements in the claim.

Q. And what's shown on the right-hand side of Exhibit 2041?

A. The characteristics and formulation of the ESI product.

Q. Have you seen this chart before, sir?

A. Yes, I helped develop it.

Q. Okay. And does Exhibit 2041 accurately reflect your views at the time of the ESI case?

A. It does.

MR. NOLAN: Your Honor, I just have an objection in terms of the labeling of this exhibit. It states, "ESI's Product Infringes Schering Patent," and it's my understanding that while Dr. Banker is an expert, he is not qualified to say that particular point. So, with that particular point, we would request that -- that the exhibit -- we don't have any objections, but we do have an objection to labeling it with a conclusion that is a conclusion for the judge.

MR. LAVELLE: Could I lay a foundation, Your Honor?

JUDGE CHAPPELL: Is this an exhibit -- is this evidence or a demonstrative exhibit?

MR. LAVELLE: Merely demonstrative of his testimony, Your Honor.

JUDGE CHAPPELL: I will sustain the objection. I'll allow it as a demonstrative. I understand it's hyperbole. It's his exhibit, it's their exhibit, so I will take that into consideration.

MR. NOLAN: Thank you, Your Honor.

BY MR. LAVELLE:

Q. Dean Banker, in the ESI case, you prepared expert reports, did you not?

A. I did.

Q. And in those expert reports, did you offer the opinion that the ESI product infringed the Schering patent?

A. I did.

Q. And is that your view today, sir?

A. It is.

Q. Would you compare the Micro-K 20 product to claim 1 of the patent using the chart on Exhibit 2041, please?

A. Claim 1 of the patent calls for a dose -- a pharmaceutical dosage form in tablet form, i.e., a tablet, for orally administering potassium chloride. The ESI product is an orally administered tablet of potassium chloride. So, they're identical.

Claim 1 speaks in the second column down, in the second bracket down, of a plurality of coated potassium chloride crystals, the amount of potassium chloride being in the range of about 68 to 86.5 percent by weight based on the total weight of the dosage unit. ESI's product contains a plurality of coated potassium chloride crystals in an amount of about 70 to about 79 percent of the total weight of the tablet, which is

entirely within the range of claim 1.

The third box down, a coating material for the individual potassium chloride crystals, the coating material comprising ethylcellulose in an amount in the range of about 9 percent to about 15 percent by weight based on the total weight of the coated crystals. The ESI product, the coating material contains ethylcellulose, the amount of ethylcellulose in the product is between 10 and about 13 percent by weight based on the total weight of the coated crystals. So, again, entirely within the claim range.

So, the first three boxes on the right would all constitute being completely within the description of the claim.

The fourth box down, at least one member selected from hydroxypropylcellulose and polyethylene glycol in an amount in the range of about 0.5 to 3 percent by weight of the total weight of the coated crystals, and in the ESI product, it contains hydroxypropylcellulose or HPC, and the amount used is 1 percent of the total weight. So, it's completely within the range.

And the last element is said ethylcellulose has a viscosity in the claim of greater than 40, and ESI uses an ethylcellulose with a viscosity of 100, which

has a range the manufacturer says of about 85 to 110. So, it would be clearly also within the claim.

Q. There's a brand name used in the last element, Ethocel 100, do you see that?

A. Yes, yes.

Q. What is that?

A. That's the brand name that Dow Chemical uses for ethylcellulose.

Q. Okay. Then what does the 100 signify next to Ethocel 100?

A. That's a good point. It's 100 cp or 100 cps.

Q. Is that related to the viscosity?

A. That's related to the viscosity, just as it is in claim 1 for the 40 cp or cps grade.

Q. Did ESI dispute that its product was a tablet?

A. No.

Q. Did ESI dispute that its product had potassium chloride in the range that the claim requires?

A. No.

Q. Did ESI dispute that its product had ethylcellulose in the range the claim required?

A. No.

Q. Did ESI dispute that its product used HPC in the coating in the range the claim required?

A. No.

Q. Did ESI dispute that its ethylcellulose had a viscosity of greater than 40?

A. No.

Q. Did ESI admit that it infringed?

A. No.

Q. Do you remember what ESI's -- do you remember ESI, in fact, contested infringement?

A. Yes, they did contest the infringement.

Q. And do you recall that they -- that their infringement related to that term "a coating material" in the claim?

A. Yes.

Q. And can you tell us briefly what ESI's position was?

A. ESI's position was that a coating material as described in the claim did not cover their product, because their product had two separate and distinct layers.

Q. Did you analyze that position?

A. I did.

Q. Did you agree with ESI's position?

A. No.

Q. Okay. I want you to look at the claim again for a moment, please, and focus on the words "coating material" there.

A. I see it.

Q. Would you tell us your opinion about what the term "coating material" means to one of skill in this art?

A. A coating material is a substance comprised of one or more layers that enrobes or coats a particle or a tablet, and the tablet may be in the form of any of a variety of tablets, sugar-coated, film-coated, compression-coated, enteric-coated.

Q. Okay. And if you use your definition of coating material in the context of claim 1, did ESI's product have a coating material?

A. It did.

Q. Would you explain that?

A. The term "coating material" to people skilled in the art means one or more layers, one or more layers of material, and a great many pharmaceutical products, such as sugar-coated tablets, are comprised of layers. There's a sealing layer, usually shellac, that's put around the tablet to keep the water out, then they put on a rounding layer, then they put on clear sugar-coated layers, then they put on color layers, then they put on a polishing layer, and that's just one example of a very common pharmaceutical product that's been used through the decades that's made up of a

plurality of layers. So, to say that a material has two layers doesn't mean it's not a coating material. It me it means it's just another coating material.

Another -- another aspect is that even when you put a material on out of a particular formulation in a Wurster tower or by spray coating or by coacervation, you're probably putting on layers of material, almost certainly you're putting on layers of material, during the application. If you think of the Power Ball with the ping-pong balls and you imagine you've got a spray head up there, the ping-pong ball goes through the spray area quickly, and you might get a third of the ping-pong ball covered, but then that same ping-pong ball has to come back around and come through a second time, maybe to get another third covered, which won't be a totally different third, and that ping-pong ball may have to go through the spray head a hundred times before it's coated, and each time, you're putting one layer of coating on top of another layer, or you're putting a layer of coating directly on the ping-pong ball.

There are two factors involved in coating. You've got to have the coating stick to the substrate, the substrate being the ping-pong ball, and you have got to have the coating stick to itself, and as the --

as the coating builds up, and as I will illustrate, you get layers, and you get openings, and you get voids.

Q. Okay.

A. So, you know, the way I see it, virtually all coatings have layers. I have a very difficult time thinking about how you'd have a coating that didn't have a layer.

Q. Thank you, sir.

Would you turn to Schering Exhibit SPX 724, please.

A. I have it.

Q. Now, this is an excerpt from the Dictionary of Pharmacy. Is that correct?

A. That's correct.

Q. Are you familiar with this work?

A. I am. We have a copy in our library in the college, a number of people have copies on their bookshelves, as I do, and you'll find it widely used in colleges of pharmacy.

Q. Is the Dictionary of Pharmacy generally accepted as reliable in the pharmaceutical and pharmacy communities?

A. It is.

Q. And who uses the book?

A. The book is used by pharmacy students, it's

used by pharmacy faculty, it's used by people working in industry and formulation labs.

Q. Thank you, sir.

Would you now look at Exhibit SPX 2042, which is an excerpt from the same Dictionary of Pharmacy?

A. Yes.

Q. Would you explain to us what the definition of "coating" is in the Dictionary of Pharmacy?

A. "Coating" appears on page 66, and it's described as, "Covering a tablet or pill with one or more protective layers;" and then they give examples, sugar-coated tablets, enteric-coated tablets, film-coated tablets and compression-coated tablets. So, they describe coverings of tablets or pills with one or more protective layers.

Q. Do you agree with that definition, sir?

A. I do.

Q. Okay. Why is that?

A. Because the definition is accurate. That's, in fact, what coatings are, coverings of one or more protective layers, and I have difficulty thinking of a coating whose morphology indicates there's only one layer. As I've indicated, even if you're coating one particular material, you're going to get layers as the different layers are laid down one after the other.

Q. Would you go back to the claim chart, Exhibit 2040, please.

A. I'm there.

Q. If you apply the definition in the Dictionary of Pharmacy of "coating" in this claim, did the ESI product infringe claim 1 of the Schering patent?

A. It would. It did.

Q. Okay. If ESI claimed that it had two separate layers -- is that correct?

A. That's correct.

Q. -- if it had two separate layers, using the dictionary definition of "coating," would it still infringe?

A. Yes, it would be described by the term "coating material." Coating material covers one or more than one layers. If they have one layer, if they have two layers, if they have 16 layers, it covers a coating material.

Q. And so if the ESI product was, in fact, mixed, would it still be covered by claim 1 using the dictionary definition?

A. It would.

Q. So, if you used the dictionary definition of "coating" in this claim, would it matter whether or not ESI's coating was mixed?

MR. NOLAN: Objection, Your Honor. The dictionary definition is a "coating," not a "coating material," and I think that it's misleading to suggest that it refers to both.

MR. LAVELLE: Your Honor, I asked him if he used the dictionary definition -- well, I'll re-ask the question.

JUDGE CHAPPELL: Okay, it's sustained, then, the objection is sustained. You're going to restate the question?

MR. LAVELLE: I am going to re-ask the question, yes, Your Honor.

JUDGE CHAPPELL: All right.

BY MR. LAVELLE:

Q. Dean Banker, if you used the dictionary definition of the word "coating" in claim 1, would ESI's product infringe claim 1?

A. It would.

Q. And using that dictionary definition of "coating," would it matter if ESI's coating had one layer or two layers or what --

A. No, no.

Q. Okay, thank you, sir.

Now, during the ESI case, ESI contended that its product had two separate and distinct layers,

correct?

A. They did.

Q. Did you analyze that factual question?

A. I did.

Q. Did you reach a conclusion with a reasonable degree of scientific certainty as to whether or not the EC and the HPC in ESI's product were, in fact, mixed?

A. I did.

Q. What did you conclude, sir?

A. They're mixed.

Q. Okay. I'd like to show you a demonstrative exhibit, SPX 2043, please.

A. I'm there.

Q. Do you recognize this exhibit, sir?

A. I do.

Q. Did you help prepare this exhibit, sir?

A. I did.

Q. Does Exhibit 2043 summarize the evidence on the mixing question in the ESI case?

A. Yes, although I can think of additional points of evidence, it does.

Q. Okay. Is it accurate?

A. It is.

Q. Looking at the left-hand column, there's a column Evidence Against Mixing?

A. Yes.

Q. Do you see that?

A. Yes.

Q. What was the evidence against mixing in the ESI case?

A. The evidence presented by ESI was that the ethylcellulose was first deposited, and then the HPC was applied, and as a result, there were two separate layers.

Q. Okay. Now, would you explain what your view of which evidence supported mixing in the ESI case?

A. A variety of bits of evidence. The first that's noted here is that the HPC is applied onto the ethylcellulose in the ESI process at a high temperature and for an extended amount of time --

JUDGE CHAPPELL: Did you have an objection?

MR. NOLAN: Yes, Your Honor. Some of the boxes on the right relate specifically to Dr. Langer's testimony, and to the extent that it would repeat it, we would object that it's cumulative.

MR. LAVELLE: I'm not going to repeat Dr. Langer's testimony other than to ask this witness if he agrees with the conclusions, Your Honor.

MR. NOLAN: My -- my understanding, Your Honor, is that to a considerable extent, Dr. Banker is relying

on Dr. Langer's report in formulating those portions of the opinion and would not add very much at this point to --

JUDGE CHAPPELL: Well, I'll sustain the objection to the extent we have a witness, as we did earlier in this trial, parroting another person's opinion; however, under the Federal Rules of Evidence, an expert has the right to rely on hearsay and other opinions, a matter you can definitely inquire into on cross examination.

MR. NOLAN: Thank you.

JUDGE CHAPPELL: You may proceed.

MR. LAVELLE: Thank you, Your Honor.

BY MR. LAVELLE:

Q. Dean Banker, would you review the evidence that in your view supported mixing in the ESI case again?

A. Yes, I'll go back to box one, if I may. The HPC is applied to the ethylcellulose at a high temperature and for an extended period of time, which promotes mixing. The temperature used is in the order of 150 degrees Fahrenheit, which would be like having a closed car in Washington in August, I suppose, inside that car. And it's applied at that temperature over periods of four to six hours. So, there's a lot of opportunity for the material to interpenetrate.

The other is -- the other factor is that water is used to apply the HPC film onto the ethylcellulose, which also promotes mixing, because water has a slow evaporational rate and will allow carrying the HPC into the pores, into the ethylcellulose coating. And as I'll discuss later perhaps, ethylcellulose, although water-insoluble, is very water-reactive. It loves water. It may not dissolve in water, but it loves water.

And thirdly, studies show an increase of potassium chloride release in ESI's product, which occurs because the HPC and ethylcellulose are mixed, and this increase in a release rate occurs after you've applied the HPC compared to the ethylcellulose alone. The pictures show no discernible boundaries between HPC and ethylcellulose.

Q. And are those the photographs that Dr. Langer testified to?

A. They are the photographs that Dr. Langer testified about.

Q. Okay. Why don't you tell us about the next point.

A. The IR fingerprint, infrared does give fingerprints of individual compounds, and when you get these individual compounds mixing at a molecular level,

you lose the individual fingerprints of each compound.

Q. And again, is this Dr. Langer's test, IR test?

A. This is Dr. Langer's test, but I would parenthetically add that I've done similar studies myself looking at polymers.

Q. Okay. What's the next element, sir?

A. The heat of fusion test, which shows that when you have individual materials, they have separate melting points due to the crystallinity. Crystallinity is a phrase for ordered structure. A crystal has atoms arranged in a very particular way, and crystalline materials have higher melting points than amorphous materials that don't have crystalline structure.

So, when you lose crystalline structure, your meting melting point drops, and that's what happens here. The two materials, when they get into a molecular level of distribution, the melting point drops, which is also an evidence of plasticization, that the films are molecularly disbursed, one within the other, and that's a field that I'm quite familiar with.

Q. And is the heat of fusion data here referred to here Dr. Langer's data?

A. It is.

Q. Would you tell us what the next point is,

please?

A. The dissolution tests from both parties show that HPC is not quickly removed, and I agree with that not only because of Dr. Langer's work but because what I know of the published literature. This is what the published literature says, too.

Q. Without repeating Dr. Langer's analysis, would you just tell us whether or not you agreed with Dr. Langer's conclusions?

A. I do, and I am familiar with these tests. I commonly do scanning electron photomicrograph work. It's right next door in the medical school. They have a wonderful microscopy lab. I go over there myself, go over there with my graduate students, and these are very standard procedures by which you do these SEMs, and they're very definitive. I train my graduate students, look at things. Don't just hypothesize, look at them. And SEM is wonderful for that, because it gives you surface morphology.

Q. What is surface morphology?

A. Surface morphology tells you what the surface construction is, how the different materials are deposited one next to the other, whether you have voids, whether you have entanglements, whether you have a smooth surface or a rough surface, and it tells you a

lot about cross-sections.

Q. Thank you. Please continue.

A. So, in summary, I find that these tests that Dr. Langer conducted, as well as the tests I've mentioned, are all indicative of mixing, and taken together I think provide virtually irrefutable evidence of mixing, but I knew mixing occurred. I knew from my work going into this -- into this work -- into this litigation that mixing occurred. I knew it from my own prior work. I knew it from my understanding of film structure. I didn't even have to look at this data.

Q. Would you explain that for us, please?

A. If we could have maybe on the ELMO some of the cross-sections of the SEMs.

Q. I'll be happy to do that, but could I just ask you first, are you going to tell us something new or different from what Dr. Langer told us?

A. Yes, I am.

Q. Then I will be happy to put up some of the -- do you want cross-sections of the HPC?

A. Yeah, let's look at -- let's look maybe at 3d, go back and find the key. The key is after SPX 713. And so 3d would be an intermediate microcapsule which has just had the ethylcellulose deposited, and --

Q. We're testing my ELMO skills here, Doctor,

just --

A. Yeah. Would you point, please, with your pen -- let me see the axis at the bottom of the picture. Would you point, please, with your pen to the 15.0 micrometer number, just show where it is for the people here in the Court?

A micrometer is a millionth of a meter, so that's a micron, and there are a series of dots above that 15 micrometer. Can you point to the series of dots -- no, down here, down lower -- down lower, just above the 15. There are 11 dots, and the 11 dots describe 10 spacings. So, each one of those spacings would be 1.5 microns.

Now, let's look at the film structure. These films have a lot of void spaces. They have a lot of open spaces. They're a network structure. They're not solid like this desk (indicating). It's not a solid thing. They're open. And if you lift this up again so we can see that 1.5 micron -- that 15 micron with 1.5 microns between dots, some of these spaces are as big as one and a half microns. Over here on the left, there are some really big open areas. A lot of the spacings are a micron.

Now, Your Honor, I have to indulge your patience a little bit and throw a number of -- another

unit of measurement at you. There's a unit of measurement called an angstrom. There are 10,000 angstroms in a micron, 10,000 angstroms in a micron. Maybe you can write that on here. One micron has 10,000 angstroms.

Now, the question is, what's the size of a hydroxypropylcellulose particle? What's the size of a hydroxypropylcellulose chain? I can go through the calculations, but the size of the chain is about a thousand microns.

MR. NOLAN: Your Honor, two objections to this. One is we, when we were putting on Dr. Levy, received objections to narrative answers and were told that Dr. Levy should curtail his answers to be specific to a particular question. This narrative answer here is objectionable.

And second, while Dr. -- while Dean Banker did discuss that he had reviewed the photomicrographs in paragraph E of page 17 of --

JUDGE CHAPPELL: Let's deal with the objections one at a time.

MR. NOLAN: Okay.

JUDGE CHAPPELL: The first objection is sustained.

What's your next objection?

MR. NOLAN: The next objection is that the depth of this analysis here is outside of the scope of his expert report, which simply said that he looked at these, and he didn't find a boundary, but --

JUDGE CHAPPELL: So, what you're saying is you're hearing something that contradicts what you've seen or heard before?

MR. NOLAN: That goes beyond what -- what I've seen or heard before in terms of -- I understand the purpose of an expert report under the federal rules is to inform the other side with as much detail as possible as to the nature of the expert's testimony, and I would believe here that we have, you know, no -- no notice of the extent of Dr. Banker's -- Dean Banker's testimony being this detailed in this area.

JUDGE CHAPPELL: Response?

MR. LAVELLE: Your Honor, if I'm not mistaken, and I don't believe I am, the micrographs -- these very micrographs are attached to Dean Banker's expert report. He discusses the micrographs in his expert report, and they were free to ask him all of these questions at his deposition. So, I'm -- I feel that they've had more than fair notice as to the likelihood that Dr. Banker or Dean Banker would testify about the micrographs.

JUDGE CHAPPELL: I'm going to overrule the objection at this time, Counselor; however, on cross examination, you're free to establish that this witness has gone beyond the opinions you were told he was going to make in this Court. At that time, we will revisit the issue. Thank you.

MR. NOLAN: Yes, Your Honor.

MR. LAVELLE: Thank you, Your Honor.

BY MR. LAVELLE:

Q. Dean Banker, let me ask you to focus on one fairly specific question. You've told us a little bit about the size of the -- of some of the voids in the ethylcellulose, correct?

A. Yes.

Q. And you've told us about the size of HPC particles. Is that correct?

A. I have.

Q. And if I understand your testimony, it's that the HPC particles are much smaller than the voids. Is that right?

A. That's true.

Q. All right. Would you explain why that is relevant to the question of whether or not the HPC interpenetrates the ethylcellulose?

A. I will, and if we also look at the description

of the surface of some of these photomicrographs, as, for example, in Figure 3b, the scientist noted that the surface had open pores smaller than five microns but in the five micron range, and in other places, she noted that the range of the pores was five microns.

Well, five microns is 50,000 angstroms. That's a huge hole for a little hydroxypropylcellulose chain to go through, even if it goes through the long way. These films are very porous, they have got holes. The ethylcellulose can very readily fit when it's dissolved and it's in water and it's wetting the surface and the solution is penetrating the film.

I don't know, Your Honor, how you could possibly produce separate films without interpenetration. I don't think it's possible using this approach of first putting down ethylcellulose and then putting down the hydroxypropylcellulose. That's my point.

Q. Thank you, sir.

I wonder if I could take you back to Schering Exhibit SPX 2043.

Your Honor, I wonder if this might be sort of a logical breaking point for the day.

JUDGE CHAPPELL: Press on, please.

MR. LAVELLE: Okay.

BY MR. LAVELLE:

Q. Let's go back to Exhibit 2043, please.

A. I'm there.

Q. Okay. I don't want to ask you anything else about the data that Dr. Langer told us about, but I do want to ask you about a few of the other elements.

A. Okay.

Q. Okay. I want to ask -- the first item you have here relates to the process conditions under which the HPC is applied.

A. Yes.

Q. Okay. Would you please go to Schering Exhibit SPX 2044, please.

Your Honor, for the record, this is an excerpt from ESI's ANDA, which is SPX 769 and I believe is already in evidence.

Sir, would you explain to us what's shown on SPX 2044?

A. Yeah, these are the processing conditions for the coating of the KCl microcaps with the Klucel, putting the Klucel or HPC on the intermediate product to produce a final product, and they've got two different batches, which basically differ in the concentration of Klucel used. In one case it's 5 percent, 5 grams of 95, and in the other case it's 10

percent, 10 grams of 90.

And the inlet -- well, they talk about the equipment. These are Wurster air suspension coaters. One is a larger unit, I believe, than the other. It's a different model anyway. They both have top sprays, the sprays are mounted above the fluidized bed. The nozzle holes are the same, 1.2 millimeters. The nozzle height is bottom located. The inlet air temperature is a fluidized air that's being used, the temperature of that fluidized air, the temperature of the air going in in degrees centigrade. And the -- to convert centigrade to Fahrenheit, it's nine-fifths C plus 32, and what's that come out to, 140, 139, something like that I think?

The air flow is the amount of air going through this coater in cubic feet per minute. The air bar is another expression of air pressure. The spray rates are in grams per minute. The spray hours are in minutes or hours, in the column on the right it's four hours. And I've described the coating solution and I've described the charges.

When you're using a 10 percent solution, you have to spray slower, because this is a very tacky, sticky, adhesive film, and if you spray too fast, the particles will all stick together.

Q. Okay, thank you.

Now, you spray the particles in at about 58 degrees centigrade?

A. Yes.

Q. And that's about 140 degrees Fahrenheit?

A. It is.

Q. Okay. Would you explain what the relevance of these process conditions are to your conclusion that there's mixing in the ESI column?

A. Yes, the heat causes things to expand. That's true if you heat a steel bar, it's true if you heat a film like this, because it increases the molecular motion, the molecular energy in the films, and the films do expand, and so that promotes penetration. The void space is greater, the pores are greater in size, and the water will go in with -- into a more energetic environment, and the water will have a greater affinity to hydrogen bond with the groups -- the hydroxyl groups on the cellulose. It will want to react with the cellulose and carry this hydroxypropylcellulose, this Klucel, with it. So --

Q. What is Klucel? I'm sorry.

A. Klucel is the trade name for hydroxypropylcellulose, the product of Hercules Chemical. So, everything in this processing promotes

the interpenetration.

Q. Okay, thank you, sir.

JUDGE CHAPPELL: Mr. Lavelle, since we started a little late today, let's try to get past 5:45, and then we'll break whenever you're through with whatever line of questioning you're on.

MR. LAVELLE: That will be fine, Your Honor. Thank you.

BY MR. LAVELLE:

Q. Now, going back to Exhibit 2043, the Evidence of Mixing chart.

A. Yes.

Q. We've talked about the first item there, haven't we, the temperature?

A. We have.

Q. And have we talked about the extended period of time that you're referring to?

A. We have.

Q. And have we talked about the water?

A. We have.

Q. Okay. The next item says, "Studies show an increase of potassium chloride release in ESI's product."

A. Yes.

Q. All right. Would you explain what that's

about, sir?

A. What that shows is that after they've applied the HPC, the release rates are faster than before they applied the HPC. So, this is evidence of the film being made more polar, being opened up, facilitating the release of the potassium chloride.

Q. Would you take a look at Schering Exhibit SPX 2045, please.

A. I'm there.

Q. Would you tell us what Exhibit 2045 is, please, sir?

A. These are ESI's release rate studies, and they're -- they took samples at two hours, four hours, six hours and eight hours. They did this dissolution release to determine how much potassium chloride had come out. In the second column next to the elapsed time, the second column from the left, this is --

Q. Just if I could interrupt you, I'm sorry, but what's the first column show?

A. The elapsed time?

Q. Yes. What is that?

A. Those are the sampling times when they took fluid and determined how much of the KCl had been released.

Q. And what is being sampled here? Just sort of

explain to us what the test is whose data was being recorded here.

A. The -- the --

JUDGE CHAPPELL: Hold on, Doctor.

MR. NOLAN: Your Honor, I believe there hasn't been a foundation laid in terms of where these studies came from. There's a reference to ESI studies, but could there be a foundation?

JUDGE CHAPPELL: Response?

MR. LAVELLE: I'll be happy to lay a further foundation. This data is right out of Dean Banker's expert reports in the -- this case and in the ESI case, and in his deposition in the ESI case, he explained that he took this data directly from data prepared by ESI.

JUDGE CHAPPELL: Well, I'm going to overrule the objection. Under Federal Rule 705, the expert doesn't have to give us the underlying data unless his questioner wants him to. The rule, though, also says you have the right to inquire into it in detail on your cross examination.

MR. NOLAN: Yes, Your Honor.

JUDGE CHAPPELL: So, for that purpose -- for that reason, your objection is overruled, and I would remind you, Dr. Banker, that I have sustained an

objection to narrative answers. So, please listen to the question and answer only the question that's pending. Thank you.

THE WITNESS: I'll try, thank you.

BY MR. LAVELLE:

Q. Let me first ask you, Dean Banker, did you attach this data to your expert report in this case?

A. Yes, I did.

Q. Did you attach this data to your expert report in the ESI case?

A. Yes, I did.

Q. Okay. Do you recall where you got this data?

A. This was from ESI itself, some of their data records, data reports.

Q. Okay, fine, thank you, sir.

And would you explain to us what is being -- what test is being described in Exhibit 2045?

A. We're looking at the percentage of potassium chloride that is being released in the second column from the left just through the ethylcellulose. That's before spraying with HPC. And in the third column from the left, after spraying with the HPC and having the completely coated crystals, and then we're looking at the percent change, increase or decrease, in release rate after applying the HPC.

Q. Okay. And the second column, is that the intermediate -- what we've been calling the intermediates here?

A. It is.

Q. And that's the potassium chloride coated with the ethylcellulose but not the HPC?

A. That's correct.

Q. And then the next column is what, sir?

A. The next column is after the HPC has been applied and you have the HPC now in place.

Q. And would you go ahead, sir, and tell us what conclusions -- first of all, what does the data show and what conclusions do you draw from it?

A. The data shows that there's an increase in release rate in the top set of numbers in the first set of paired lots in every case. The increases may not be large, but they're consistent. They occur at every time point.

And in the second set of paired lots, there's also an increase in the release rate, not as great as above, and in three cases out of four, it's an increase in release. The last point, most of the drug is out, so it's not too surprising there's little change or there's a negative change.

Q. Okay. Why is the release rate data relevant to

whether or not there's mixing in the ESI product?

A. Because the hydroxypropylcellulose, as it interpenetrates the ethylcellulose, can facilitate the release of the potassium chloride. The HPC will hydrate as water penetrates into the -- into the film, and what happens with these coated crystals in the stomach or in this beaker is that water does penetrate the coating, and after it penetrates the coating, it dissolves the potassium chloride, and then the potassium chloride in solution comes out.

As the potassium -- as the water goes through and the hydroxypropylcellulose is hydrated, it swells, and it forms some channels to facilitate water in, potassium chloride out. So, you would expect if there's interpenetration, you would expect to see an increase in release rate.

Q. Okay. If all of the HPC were sitting on the outside of the ESI capsule on a separate layer, what would you anticipate seeing in terms of the impact of the HPC on the release rate of the potassium chloride?

A. I wouldn't expect to see any impact between the second and third columns.

Q. Okay, thank you, sir.

And what conclusion do you draw from the data on Exhibit 2045 about the -- whether or not there's

mixing in the ESI product?

A. It's -- it's further evidence of mixing.

Q. Okay.

Excuse me one second, Your Honor.

JUDGE CHAPPELL: Okay.

(Counsel conferring.)

MR. LAVELLE: I'm trying to find an exhibit number, Your Honor.

JUDGE CHAPPELL: Take your time.

MR. LAVELLE: Your Honor, may I approach the witness?

JUDGE CHAPPELL: Yes, you may.

BY MR. LAVELLE:

Q. Dean Banker, I want to hand you Schering Exhibit SPX 746. Would you tell us what that is? Just first of all, what is 746, the whole document?

A. It's the dissolution study of paired lots of ESI Lederle's microencapsulated caps, intermediate and compressible.

Q. And what you're looking at on that page is the data we've just been talking about?

A. Yeah, it's the same data as on the screen here.

Q. And I wonder if you would tell us what that volume is you're holding in your hand.

A. This is my expert report dated the 30th day of

September, 2001.

Q. Okay, thank you.

And I wonder if you can tell by looking at your expert report, can you identify for us any better what the source of the data you consulted in preparing this release rate data?

A. It's out of their apparently confidential development work where they used a standard dissolution testing apparatus, and they used a potassium ion selective electrode, which is a way of electronically measuring how much potassium is in solution, and it's basically I think a valid test. They used a USP method, United States Pharmacopeia method, method one. They used one-gram samples. They might have used a larger sample, one and a half grams, corresponding to the dose. They used deionized water, they used body temperature, and they took 10-mil samples at the two-hour intervals. I think it's a valid test.

Q. Thank you, sir.

And just for the record, Your Honor, the witness has been reading from SPX 746, tab O, and the pages of the tab bear ESI production numbers 27 -- EXP 274, 275.

JUDGE CHAPPELL: Okay.

MR. LAVELLE: Thank you, Your Honor.

BY MR. LAVELLE:

Q. Would you go back to Exhibit 2043 for just a moment and let's finish up this line.

If I could just have two more minutes, Your Honor, I can finish up this chart.

JUDGE CHAPPELL: You've got them.

THE WITNESS: I have it.

MR. LAVELLE: Thank you.

BY MR. LAVELLE:

Q. Sir, overall, did you come to a conclusion with a reasonable degree of scientific certainty as to whether or not there was mixing in the ESI product?

A. According to every test conducted, mixing was indicated, and based on the cumulative data, which we often look for in science, do tests support one another or do tests contradict one another, and if tests contradict one another, you'd perhaps want to look at a third or a fourth test. In this particular case, every single test indicated mixing, and as I've indicated earlier from a physical chemical particle size standpoint, I don't know how you could avoid mixing.

Q. Okay. Did you consider in reaching your opinion the views that Dr. Hopfenberg expressed in his evaluation?

A. I did.

Q. And would you tell us what weight you gave those views?

A. Very little. Very little weight. I'll just say that, not make any other comment.

Q. If the Schering patent were interpreted to require mixing, did you have an opinion on whether or not the patent so construed would be infringed from your technical perspective?

A. I absolutely did.

Q. And what was your opinion?

A. Well, the patent, based on the claim chart comparison we had, is literally infringed, and mixing is -- is clearly present. So, I don't know how you could reach any other conclusion, at least I couldn't reach any other conclusion in my mind other than infringement was there.

MR. LAVELLE: Thank you, sir.

Your Honor, this would be a good place to stop for today. I am at the end of this line.

JUDGE CHAPPELL: Okay, thank you, Mr. Lavelle.

We will adjourn for the night. We will start back in the morning at 9:30.

C E R T I F I C A T I O N  O F  R E P O R T E R

DOCKET/FILE NUMBER: 9297

CASE TITLE: SCHERING-PLOUGH/UPSHER-SMITH

DATE: FEBRUARY 11, 2002

I HEREBY CERTIFY that the transcript contained herein is a full and accurate transcript of the notes taken by me at the hearing on the above cause before the FEDERAL TRADE COMMISSION to the best of my knowledge and belief.

DATED: 2/12/02

SUSANNE BERGLING, RMR

C E R T I F I C A T I O N  O F  P R O O F R E A D E R

I HEREBY CERTIFY that I proofread the transcript for accuracy in spelling, hyphenation, punctuation and format.

DIANE QUADE